Supreme Court, U.S.
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IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, AND G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq*., allows a state to use authority under that statute to compel drug manufacturers to subsidize price discounts on prescription drugs for non-Medicaid populations?

2. Whether a state may circumvent the Commerce Clause prohibition against regulating or taxing wholly out-of-state transactions by requiring an out-of-state manufacturer, which sells its products to wholesalers outside the state, to pay the state each time one of its products is subsequently sold by a retailer within the state?

PARTIES TO THE PROCEEDING

The Petitioner is the Pharmaceutical Research and Manufacturers of America ("PhRMA"). The Respondents are Kevin Concannon, the Commissioner of the Department of Human Services of the State of Maine, and G. Steven Rowe, the Attorney General of the State of Maine.

Petitioner PhRMA is a not-for-profit incorporated membership organization. There are no parent corporations or publicly held companies that own 10% or more of PhRMA's stock. A list of PhRMA's members may be found at http://www.phrma.org/who/memlist.phtml.

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OPINIONS BELOW

The opinion of the court of appeals (App. 1-53) is reported at 249 F.3d 66 (1st Cir. 2001). The order of the court of appeals declining to act on PhRMA's petition for rehearing *en banc* (App. 54-56) is unreported. The opinion of the district court (App. 57-72) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 16, 2001. On June 13, 2001 the court of appeals entered an order denying rehearing and declining action on PhRMA's timely petition for rehearing *en banc*. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Article I, § 8, cl. 3 of the Constitution providing that "The Congress shall have Power...to regulate Commerce...among the several States...".

2. Article VI of the Constitution providing that "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof...shall be the supreme Law of the Land...".

3. Section 1927 of the Social Security Act, 42 U.S.C. § 1396r-8, governing the Medicaid prescription drug rebate program (App. 73-84).

4. The Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599), providing for the establishment and operation of a "Maine Rx" program to subsidize retail drug purchases (App. 85-108).

STATEMENT OF THE CASE

Maine seeks to compel out-of-state drug manufacturers, who sell their drugs to wholesalers outside Maine, to subsidize retail price discounts for Maine residents who purchase drugs in Maine. The First Circuit held that exacting such a subsidy does not violate the dormant Commerce Clause's prohibition on extraterritorial regulation by the states.

Maine seeks to enforce payment of this subsidy by using authority granted under the federal Medicaid statute, even though the new Maine subsidy program is wholly unrelated to Medicaid. Maine proposes to do so by limiting *Medicaid* patients' access to the drugs of manufacturers who do not submit to Maine's mandated subsidies for *non*-Medicaid patients under the new state program. The First Circuit held that Maine may use its authority under the federal Medicaid statute to compel such subsidies, while the D.C. Circuit has held that the Medicaid statute does not empower the governing federal agency to authorize states to use the Medicaid statute as leverage to extend Medicaid discounts to non-Medicaid populations.

Review by this Court is warranted to correct the First Circuit's erroneous reading of the limits to which the Medicaid statute may be stretched, and to resolve the conflict between the First Circuit and the D.C. Circuit over that important federal statutory question. Review is also warranted to clarify that states may not evade the Commerce Clause's prohibition against regulating wholly out-of-state sales transactions by demanding payments on goods sold out-of-state that are then resold by third parties inside the state. Both issues are of national importance. As the decision below (from Maine) and the decision in the D.C. Circuit case (from Vermont) illustrate, the harmful phenomenon of state efforts to use Medicaid leverage to exact non-Medicaid subsidies is fast spreading, with more

than two dozen states poised to enact laws similar to Maine's. Thus, this Court's resolution of the questions presented by this petition is urgently needed.

I. The Maine Rx Program

1. Declaring that the prices charged by drug manufacturers for their products are "excessive," Maine's Act to Establish Fairer Pricing for Prescription Drugs (the "Act"), 22 Me. Rev. Stat. Ann. § 2681 *et seq*. (App. 85-108), requires drug manufacturers to subsidize retail price discounts to Maine residents under a new state program called "Maine Rx." The Act requires all drug manufacturers whose products are ultimately sold in Maine to enter into "rebate agreements" with the state, and to make payments to subsidize such discounts—regardless of whether the manufacturers actually sell the drugs in Maine. 22 Me. Rev. Stat. Ann. § 2681(3).

Under these agreements, a manufacturer must make a "rebate" payment to the State for each unit of a drug that is sold by a Maine pharmacy to a participating Maine resident. The Act requires a manufacturer to make such payments even if the manufacturer is a complete stranger to that in-state sales transaction, and even if the manufacturer never engaged in *any* sales transaction in Maine leading up to that retail purchase. It is undisputed that there are currently no drug manufacturers located in Maine, and that manufacturers make few (if any) sales to anyone in Maine, much less retail sales to consumers. Typically, pharmaceutical manufacturers sell drugs to national and regional wholesalers (all but one of which are also outside Maine) in transactions that take place in other states.

The "rebate" required from a manufacturer has no relationship to the in-state sales price. Instead, it is tied to a national price benchmark: the Maine Commissioner of Human Services is instructed to use his best efforts, backed by the sanctions of the Maine law, to secure a rebate on each

drug that is at least as large as the rebate that the manufacturer pays nationwide in the federal Medicaid program.[1] (The Medicaid rebate, in turn, is a function of the manufacturer's average price to customers nationwide, or of its single best price to any commercial customer in the country.) Implementing the Act's mandate, Respondent Concannon presented manufacturers with a form Maine Rx Rebate Agreement, for signature no later than November 1, 2000, that dictated payment of "the Medicaid Rebate amount." (JA 64, 67)[2]

Manufacturer "rebate" payments are to be paid into a dedicated state fund, which Maine will use to reimburse local pharmacies for prescription drug discounts for participating Maine residents.[3] Maine makes no net contribution to these subsidies; they are to be funded entirely by the payments extracted from manufacturers.

2. The Act enforces its requirement that manufacturers pay for these Maine Rx subsidies by

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[1] The federal Medicaid program pays for Medicaid beneficiaries' prescription drugs using federal and state funds. For their drugs to be covered in this program, manufacturers must pay a per-unit rebate based on Medicaid sales in each state. 42 U.S.C. § 1396r-8. The nationwide Medicaid rebate for a given drug is calculated based on data about the manufacturer's pricing around the country, using a formula set forth in the Medicaid statute. 42 U.S.C. § 1396r-8(c)(1).

[2] Citations with the notation "JA" refer to items in the parties' Joint Appendix before the court of appeals.

[3] Maine residents will tender a "Maine Rx" card at the pharmacy, and will be charged a discounted price set by the state. The state will then use the funds obtained from manufacturers to reimburse pharmacies for those discounts, plus "professional fees" of at least $3 per prescription. 22 Me. Rev. Stat. Ann. § 2681(5), (6).

threatening them with sanctions under the federal Medicaid program if they do not. If a manufacturer refuses to pay Maine Rx rebates, its drugs will be subject to a "prior authorization" requirement in the Medicaid program in Maine. 22 Me. Rev. Stat. Ann. § 2681(7). A drug subject to "prior authorization" will not be covered by Medicaid unless a physician first obtains special permission from state Medicaid officials to prescribe it to a Medicaid patient. Prior authorization is commonly used to limit prescription of drugs that present medical risks or that are vulnerable to over-prescription, posing risks to the Medicaid patient or program. Here, however, the sole purpose of subjecting drugs to prior authorization is to reduce non-complying manufacturers' sales and thereby to coerce them into joining the Maine Rx program. Prior authorization achieves that effect by deterring doctors from prescribing the restricted drugs and inducing them to switch their patients to other, potentially second-choice, medications.

II. The District Court's Order

On August 10, 2000, PhRMA filed its complaint for declaratory and injunctive relief in the U.S. District Court for the District of Maine, claiming that the rebate provisions of the Act violated the Supremacy Clause and the Commerce Clause of the U.S. Constitution. On October 26, 2000, finding PhRMA's likelihood of success on the merits of these claims to be "overwhelming," the district court issued a preliminary injunction against the implementation of the Maine Rx rebate program. (App. 72)

Judge Hornby held that Maine had exceeded the territorial limits of its regulatory authority under the Commerce Clause. He found that, by exacting rebates from drug manufacturers who sell their drugs outside the state, the Maine Rx Program unavoidably—and unconstitutionally—regulates those out-of-state sales. (App. 64-66) The district court rejected Maine's efforts to escape

Commerce Clause scrutiny by claiming the status of a "market participant." (App. 64)

The district court also ruled that Maine's use of its Medicaid "prior authorization" power to penalize manufacturers who do not subsidize discounts under the separate Maine Rx program posed an obstacle to the delivery of Medicaid benefits. Because of that conflict, the district court found the use of prior authorization to enforce Maine Rx rebate collections to be preempted by the Medicaid statute. (App. 67-70)[4]

III. Proceedings in the First Circuit

On May 16, 2001, a First Circuit panel, sitting pursuant to an emergency certification under 28 U.S.C. § 46(b) and including no active judges of the court, reversed and vacated portions of the preliminary injunction—even while describing the appeal as a "close case." (App. 28)

The court of appeals held that, because the pharmacy sales of the drugs take place in Maine, it does not constitute "extraterritorial" regulation for Maine to require out-of-state manufacturers to subsidize those in-state retail sales, even

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[4] PhRMA also claimed in the district court that other so-called "anti-profiteering" provisions of the Act violated the Commerce Clause to the extent they purported to regulate transactions occurring outside Maine. *See* 22 Me. Rev. Stat. Ann. § 2697(2). The district court agreed and preliminarily enjoined their enforcement in connection with out-of-state transactions. (App. 60) Maine did not appeal from that portion of the district court's order, and hence the "anti-profiteering" provisions are not before this Court (except as evidence of the Act's compulsory design). The district court concluded that PhRMA's Commerce Clause challenge to a related "anti-retaliation" provision, prohibiting manufacturers from reducing or altering the distribution of drugs in Maine in response to the Act, was not ripe. (App. 61)

though the manufacturers sell their drugs, not to consumers or even pharmacies in Maine, but to wholesalers outside Maine.

The court also held that Maine's use of the Medicaid "prior authorization" sanction to compel payment of subsidies for *non*-Medicaid patients under Maine Rx does not conflict with the federal Medicaid program. The court declined to find such conflict in the absence of evidence that prior authorization must result in the denial of medically necessary drugs to Medicaid patients. (App. 16) The court also expressed the view that Maine Rx subsidies might benefit the Medicaid program indirectly by keeping some Maine residents from needing Medicaid assistance at some future date. (App. 13)

PhRMA timely filed a petition for rehearing *en banc*. The court of appeals' emergency panel denied the subsumed petition for rehearing, but announced in an order dated June 13, 2001, that "there can be no action taken" on the petition for rehearing *en banc* because all but one of the active judges of the court of appeals were recused. The one active judge of the First Circuit who was not recused—Chief Judge Torruella—stated that he supported rehearing *en banc* "based on the opinion of the District Court." (App. 55)

The court of appeals' decision constitutes a final judgment on the merits of Petitioner's Commerce Clause and Supremacy Clause challenges to the Act. On PhRMA's motion to stay the mandate pending filing of this petition, the court of appeals entered an order staying its mandate until July 31, 2001.

REASONS FOR GRANTING THE WRIT

I. The First Circuit's Decision on the Medicaid Issue Is in Error, and Conflicts with a Decision of the D.C. Circuit.

The First Circuit's conclusion that Maine may use its authority under the federal Medicaid statute to compel drug manufacturers to provide discounts to individuals not eligible for Medicaid is both incorrect and in conflict with a decision of the D.C. Circuit. The D.C. Circuit held that Congress in the federal Medicaid statute does not authorize states to compel drug manufacturers to pay for Medicaid discounts for non-Medicaid populations.

A. The First Circuit Erred in Holding that the Federal Medicaid Statute Allows a State To Require Manufacturers To Provide Discounts for Non-Medicaid Populations.

In the Medicaid program, a prescribing physician must contact the state Medicaid authority and provide written documentation to justify prescribing a "prior authorized" drug to his or her Medicaid patient. *See* Maine Medical Assistance Manual, Ch. II § 80.07-3, -4 (JA 177-79). The burden of obtaining prior authorization deters—indeed, is designed to deter—physicians from prescribing the drugs in the first instance. Medicaid beneficiaries' access to their doctors' preferred drugs is therefore necessarily impeded. (JA 122-25)

Prior authorization has legitimate uses in the Medicaid program. It can, for example, be used to prevent abuse or over-prescription of popular but expensive medications, thereby benefiting Medicaid patients and promoting Medicaid's cost-effective operation. Although prior authorization restricts the provision of physicians' first-choice drugs to Medicaid patients, that burden is deemed to be outweighed by the benefits to the Medicaid program.

The federal Medicaid statute authorizes states to impose prior authorization requirements for prescriptions paid for by Medicaid, subject to certain procedural safeguards. 42 U.S.C. § 1396r-8(d)(1), (5).

Here, the purpose of the Act's imposition of Medicaid prior authorization is not to benefit the federal Medicaid program or Medicaid beneficiaries, but to coerce funding by drug manufacturers of an unrelated state program. Because Medicaid prior authorization by definition restricts the delivery of drug benefits to Medicaid patients, its imposition to effectuate the Maine Rx program both burdens and conflicts with the Medicaid program.

This court's jurisprudence is clear: state laws that impose "obstacles to the accomplishment and execution of the Congressional objectives" of the federal law—here, Medicaid—cannot stand. *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983). This is just such a law. Congress intended to provide prescription drugs to Medicaid patients, a class identified by federal law that does not extend to the entire citizenry of Maine. *See* 42 U.S.C. § 1396, 1396a(a)(10)(A), 1396d(a). The flow of those prescription drug benefits will be restricted by the state under Maine Rx.

The court of appeals misunderstood the nature of the "obstacle" or "interference" with the Medicaid program that Maine Rx causes. Depriving patients of necessary drugs or directly harming their health would of course offend the Medicaid statute. But it is not necessary to await evidence of actual, life-threatening harms to Medicaid patients in order to find that Maine Rx prior authorization interferes with Medicaid's provision of medical services to Congress's intended beneficiaries. *See* 42 U.S.C. § 1396, 1396r-8. Failure to pay Maine Rx rebates will trigger prior authorization of at least *some* drugs—drugs that, "but for" Maine Rx, would be accessible to Medicaid patients and doctors without delay, and paid for by Medicaid without

reservation. This interference with the physician's choice of treatments for Medicaid patients is inherent and inescapable in the structure of the program. The physician is now forced to choose between a first-choice drug that requires prior authorization and a second-choice drug that does not. Maine Rx-triggered prior authorization also consumes federally-funded Medicaid resources, such as the time and resources of the Medicaid Drug Utilization Review Committee that lists drugs for prior authorization, and of the Medicaid officials who must review doctors' prior authorization requests.

Without a Medicaid purpose, the Maine Rx use of prior authorization is necessarily inconsistent with the "best interests" of Medicaid patients, 42 U.S.C. § 1396a(a)(19), and the Medicaid program. The court of appeals mistakenly required factual proof of realized harms to patients. No such human experimentation should be required to recognize that Maine Rx prior authorization is preempted as a matter of law, for the program cannot possibly be in the "best" interests of Medicaid patients if it serves *no* interest of the Medicaid program.

In reversing the district court, the court of appeals found it significant that the Medicaid statute does not expressly bar states from co-opting Medicaid prior authorization authority for non-Medicaid purposes. But the lack of an express prohibition on using Medicaid powers for non-Medicaid purposes is no license to do so. As the district court recognized, the logical implication of that approach—that Medicaid prior authorization can be put to *any* purpose—is stunning: "If Maine can use its authority over Medicaid authorization to leverage [rebates for Maine Rx], then it can just as easily put the rebates into a state program for highway and bridge construction or school funding." (App. 68) Congress cannot be deemed to have allowed the tools it provided for the operation of the federal

Medicaid program to be used for any other purpose that a state may imagine.

The court of appeals reasoned that Maine Rx subsidies might indeed serve a "Medicaid purpose" by reducing impoverishment, thus keeping Maine residents off Medicaid rolls. (App.13) The same reasoning, however, would permit Maine to compel drug manufacturers to subsidize public housing, job training programs, and any number of other public projects that would boost Maine residents' income and keep them off Medicaid. There is simply no suggestion that Congress intended to permit states to put Medicaid beneficiaries' access to prescription drugs at risk in order to fund other budget items or promote local non-Medicaid social goals. That Congress did not affirmatively prohibit states from doing so is insufficient to defeat an "obstacle" preemption claim, and in any event, is explicable by the fact that Maine's forced subsidy so far departs from the Medicaid program that Congress could not have been expected to foresee and prohibit it. As Judge Hornby explained, "[i]t may never have occurred to Congress that the Medicaid program could by hijacked to provide leverage for other purposes." (App. 69 n.12)[5]

B. The First Circuit's Decision Conflicts with a Decision of the D.C. Circuit.

The First Circuit's holding that a state may use its authority under the federal Medicaid statute to require drug manufacturers to provide discounts to non-Medicaid consumers is also incompatible with a recent ruling of the

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[5] The limited legislative history of the Medicaid drug benefit and the federal Health Care Financing Agency's ("HCFA") proposed implementing regulations contemplate the use of prior authorization only in narrow circumstances, all of which further Medicaid objectives. *See* the district court's exposition of this history at App. 69 n.12.

Court of Appeals for the District of Columbia Circuit. That court, in *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001), held that Congress has *not* authorized the U.S. Department of Health and Human Services ("HHS") to permit states to "require pharmaceutical manufacturers to provide substantial discounts to individuals not otherwise covered by state Medicaid programs." 251 F.3d at 226. If the federal Medicaid statute does not authorize HHS to permit a state to require manufacturers to subsidize discounts to non-Medicaid populations, the statute cannot be meant to empower states like Maine to impose such requirements on manufacturers directly.

In *Thompson*, Vermont—like Maine—sought to extend Medicaid prescription drug discounts to individuals who were not eligible for Medicaid benefits. Rather than use Medicaid prior authorization to exact drug rebates in a non-Medicaid program, Vermont obtained a statutory waiver from HHS authorizing it to obtain rebates for non-Medicaid patients directly under the auspices of the Medicaid program. PhRMA challenged Vermont's waiver, whose intent and effect were identical to those of the Maine Rx program: the state would use authority under the Medicaid program (waiver authority in Vermont, prior authorization authority in Maine) to compel drug manufacturers to fund Medicaid-level discounts for patients not covered by the Medicaid program.

The D.C. Circuit held that the federal Medicaid statute does not permit such a scheme; the First Circuit held that it does. The decisions of the First and D.C. Circuits are therefore in conflict. Specifically, the First Circuit held that Maine may administer the Medicaid program in a manner that extends Medicaid benefits to non-Medicaid populations; the D.C. Circuit concluded that the Medicaid statute did not authorize HHS or Vermont to secure Medicaid discounts from drug manufacturers for non-Medicaid patients. The

First Circuit permitted Maine to stretch its Medicaid authority to extra-Medicaid ends; the D.C. Circuit denied that leeway to HHS and Vermont.

Review by this Court is necessary to resolve this conflict in federal statutory interpretation. Even though the D.C. Circuit case concerned the scope of administrative authority to permit state action pursuant to Medicaid while this case concerns that of a state in the first instance, the underlying issue is identical: may the leverage of Medicaid be used to compel subsidies from manufacturers for persons outside the Medicaid program. The D.C. Circuit correctly answered that question in the negative, and the petition should be granted here to ensure that the same answer applies nationwide. The Medicaid program operates throughout the country, providing medical care to millions of beneficiaries. Many more states have announced plans to enact their own versions of the Maine Rx program (*see* Part III *infra*). Interpretations of the scope of Medicaid statutory authority on a matter of such national importance should not be permitted to vary from one circuit to the next.

II. The Decision Below Allows the State to Circumvent the Commerce Clause's Prohibition Against State Regulation of Wholly Out-of-State Transactions.

The court of appeals permitted Maine to circumvent the Commerce Clause's prohibition against extraterritorial regulation. Few prohibitions of the structure of federalism are so clear or compelling as the one that a state may not regulate economic transactions that take place beyond its borders. Whether the Maine Rx program is characterized as an extraterritorial regulation of price or of revenue, as an impermissible tie between in-state and out-of-state prices, or as akin to a tax, it violates that prohibition. Thus, Maine's requirement that out-of-state manufacturers, who sell their products to out-of-state wholesalers in wholly out-of-state transactions, remit a portion of the out-of-state sales price to

subsidize in-state retail purchases by Maine residents runs afoul of the negative implications of the Commerce Clause.

A. The Maine Rx Rebates Regulate Wholly Out-of-State Transactions

It is axiomatic that a state "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there." *Baldwin v. G.A.F. Seelig*, 294 U.S. 511, 521 (1935) (internal punctuation omitted). As this Court has repeatedly confirmed, a state may not dictate the terms on which buyers and sellers do business outside the state. *See, e.g., Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 583-84 (1986); *Healy v. The Beer Institute*, 491 U.S. 324, 338 (1989). Three factors help identify a state statute with an unconstitutional extraterritorial reach or effect that will render it virtually *per se* invalid: (i) whether the regulation is applied to commerce "wholly outside of the State's borders," (ii) whether "the practical effect" of the regulation is to control such commerce, and (iii) what effect the regulation has on other states' regulations, as well as what effect would result "if not one, but many or every, State adopted similar legislation." *Healy*, 491 U.S. at 336.

Consistent with these teachings, states may not regulate the price or terms on which goods are sold outside the state simply because the goods are later re-sold within the state. Rather, the courts have limited the reach of a state's powers to transactions that actually take place within the state. *See Baldwin*, 294 U.S. at 528; *Dean Foods Co. v. Brancel*, 187 F.3d 609, 614-15 (7th Cir. 1999); *Louisiana Dairy Stabilization Bd. v. Dairy Fresh Corp.*, 631 F.2d 67 (5th Cir. 1980); *Schwegmann Bros. Giant Super Mkts. v. Louisiana Milk Comm'n*, 365 F. Supp. 1144, 1156 (M.D. La. 1973), *aff'd mem.* 416 U.S. 922 (1974).

The court of appeals' decision would allow Maine to circumvent the Commerce Clause prohibition delineated in

these cases. The Act regulates manufacturers' sales outside the state, and thus impermissibly extends that State's reach extraterritorially. But Maine seeks to reach these out-of-state sales under the guise of regulating the in-state sales that follow from them.

Virtually all manufacturers' sales of prescription drugs occur outside of Maine, in direct, arms-length transactions with wholesalers and distributors. Typically, both the manufacturers and their customers (independent wholesalers and distributors) are located outside Maine. More important, the drugs are usually delivered at the manufacturers' facilities outside Maine, and title and risk of loss pass outside Maine. Frequently the drugs are then shipped by common carrier to warehouses and distribution centers outside Maine. (JA 54-55, 57-58, 75-76, 87-88, 100-01) The wholesalers and distributors then sell the drugs to their customers, including customers in Maine.

Nevertheless, Maine Rx will exact a payment from a drug's manufacturer every time the drug crosses the pharmacy counter in Maine, even though the out-of-state manufacturer sold that product outside Maine to a wholesaler in another state and had no further role in the transactions that took the drugs to Maine. That levy necessarily changes the economic terms of the only sales transactions in which manufacturers *are* engaged—namely, sales outside the State—by effectively reducing the revenues the manufacturers receive for their products from their wholesale customers. The manufacturer who is assessed the rebate will receive less net revenue on each wholesale transaction involving drugs that find their way to Maine (a result the manufacturer does not control and cannot predict). As the district court recognized, "whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced when the drug comes to Maine." (App. 66) Whether Maine is understood as regulating price or revenue in manufacturers' out-of-state

wholesale transactions, it is impermissibly regulating outside its borders.

The court of appeals erred in treating the Act as "simply regulat[ing] activity that occurs in state"—namely the consumer's retail purchase of drugs at a Maine pharmacy. (App. 24) That retail sale of a drug in Maine serves only as the trigger for the required rebate. What matters for Commerce Clause analysis is the target of the regulation—the manufacturer—and where that target does its business. The out-of-state manufacturer is a stranger to the "triggering" in-state transaction at the pharmacy. The court ignored the fact that the manufacturer is remote from that triggering event and that the "practical effect" of the Act is to regulate the manufacturer's commerce occurring "wholly outside of the state's borders." *Healy*, 491 U.S. at 336. The court of appeals thus incorrectly allowed Maine to circumvent the Commerce Clause's prohibition on extraterritorial regulation.

The court of appeals attempted to distinguish *Healy*, *Brown-Forman*, and *Baldwin* on the ground that they prohibit only the express regulation of out-of-state price terms, not the regulation of manufacturers' profits in out-of-state sales. (App. 22) This distinction presents a novel question warranting this Court's attention: is the dormant Commerce Clause's bar on extraterritorial regulation limited solely to the explicit regulation of price terms? May a state evade the bar of *Healy*, *Brown-Forman*, and *Baldwin* by explicitly regulating only the non-price terms of out-of-state transactions?

Nothing in the *Healy* line of cases suggests that the extraterritoriality prohibition is limited to extraterritorial price controls. To the contrary, *Healy* simply holds that a state law with the "'practical effect' of regulating commerce occurring wholly outside the State's borders" is *per se* invalid under the Commerce Clause. 491 U.S. at 332. The term "commerce" is not restricted to price. For example,

this Court has also struck down as extraterritorial a business takeover act that lacked any pricing dimension whatsoever, in *Edgar v. MITE Corp.*, 457 U.S. 624 (1978).

If a state is barred from regulating prices out-of-state, it surely should not be free to achieve the same effect by regulating quantity, profit or other ancillary terms of sale instead. The court of appeals' distinction between the regulation of out-of-state price terms (which this Court has held to be prohibited) and the regulation of out-of-state revenue (which the First Circuit would permit) makes no economic sense. Absent intervention by this Court, the First Circuit's flawed distinction will stand as a new—and erroneous—principle of dormant Commerce Clause jurisprudence.

Maine had any number of constitutionally legitimate tools at its disposal for reducing drug costs for its citizens. It might constitutionally have raised funds for the Maine Rx program by imposing a tax on retail pharmacy sales within the state. It might constitutionally have entered the pharmaceutical market as a wholesale purchaser, exercising its own market power to reduce retail prices through bulk purchases—a form of market participation the court of appeals correctly found not present in the Act, *see* App. 20. But Maine chose to do none of these things, and instead attempted to circumvent the Commerce Clause. That attempt should not be permitted to succeed.[6]

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[6] Given the high degree of integration in our national economy, it is especially dangerous to permit the kind of fragmentation Maine proposes—namely, allowing states to compel in-state subsidies by upstream manufacturers doing business in other states. Other issues may soon capture a state legislature's attention—*e.g.*, levies on Texas oil refiners to fund New Hampshire heating oil subsidies, or compulsory rebates from California chip manufacturers to reduce the price of computers in New Jersey. According to the court of appeals, the Commerce

B. The Maine Rx Rebates Are Impermissibly Tied to Out-of-State Prices

The First Circuit's refusal to apply this Court's extraterritoriality precedents is even more disturbing in light of the fact that the Act *does* have the effect of regulating out-of-state prices. Like the state laws at issue in *Baldwin*, *Healy*, and *Brown-Forman*, the Act expressly ties in-state prices to out-of-state prices. It specifies that the rebate required of manufacturers shall equal or exceed the rebates required around the country under Medicaid and other federal programs. 22 Me. Rev. Stat. Ann. § 2681(3), (4).

This use of an out-of-state price benchmark for Maine's in-state mandatory rebate offends the Commerce Clause in just the ways noted in *Brown-Forman* and *Healy*: the regulated business can no longer set its out-of-state price based solely on the out-of-state market conditions. Instead, when setting prices in out-of-state (or here, federal and nationwide) transactions, the drug manufacturers now must also factor the in-state price ramifications into their pricing calculations.[7] Such price-tying has been explicitly condemned as *per se* invalid by this Court because it

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Clause places no limits on a state's extraterritorial reach or its creativity, so long as a good is ultimately sold within that state.

[7] The federal prices to which Maine Rx rebates are tied are variable, and change with manufacturers' commercial pricing decisions. Specifically, the federal Medicaid rebate amount for each brand-name drug is a function of the manufacturer's national average price to retail customers and the manufacturer's "best price" to any commercial customer in the country. 42 U.S.C. § 1396r-8(c)(1). Although calculated under a statutory scheme, these "national prices" that set the benchmarks for Maine Rx rebates are susceptible to the same market pricing dynamics and extraterritorial effects as the state-specific prices described in *Healy* and *Brown-Forman*.

interferes with market-based competition in the out-of-state markets. *See, e.g., Healy*, 491 U.S. at 332.

The court of appeals did not consider the Commerce Clause's prohibition on extraterritorial price-tying to be violated because the Act directs the Commissioner to use his "best efforts" to "negotiate" the rebate, and does not unequivocally dictate that price. But the reality is that there is nothing to "negotiate"—in the Act's own words, the "rebate [is] *required* from a manufacturer" under an agreement that the manufacturer "*shall enter into*." 22 Me. Rev. Stat. Ann. § 2681(3), (4) (emphasis supplied). Even more powerfully, if a manufacturer refuses to pay the rebate, its drugs become subject to prior authorization. Putting form over substance, the court of appeals again permitted the state to evade the strictures of the Commerce Clause.

C. The Maine Rx Rebates Tax Wholly Out-of-State Transactions

The court of appeals' decision also allows Maine to circumvent another line of Commerce Clause precedents: *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977), and its companion tax cases. While not ostensibly a tax or duty, the Maine Rx rebate requirement has the same effect as a sales tax or import assessment on the manufacturer's products—it demands payment to the state for each unit of the manufacturer's goods that are sold in Maine pharmacies.[8] Analogizing the Act to a tax further

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[8] Maine has declined to characterize the Maine Rx program as a state tax or a duty on imports (JA 228); rather, the parties invoked the interstate tax immunity cases to illuminate the issues here by analogy. Although the court of appeals declined to address this line of argument (App. 27 n.11), it was briefed and argued by both parties below. *Cf. Nixon v. Fitzgerald*, 457 U.S. 731, 743 n.23 (1982) (Court may decide purely legal question not passed on below).

underscores the court of appeals' error in allowing Maine to circumvent this Court's Commerce Clause precedents.

The *Complete Auto* line of decisions establishes that the mere fact that a product winds up within the state is an insufficient basis upon which to impose a tax on out-of-state entities. *Id.* at 277-79. The Maine Rx rebate thus lacks the "'definite link . . . between a state and the person, property or transaction it seeks to tax'" that the Commerce Clause requires. *National Bellas Hess v. Department of Revenue of Ill.*, 386 U.S. 753, 756 (1967) (quoting *Miller Bros. Co. v. Maryland*, 347 U.S. 340, 344-45 (1954)) (overruled in part on other grounds, *Quill Corp. v. North Dakota*, 504 U.S. 298 (1992)); *see also Complete Auto*, 430 U.S. at 277-79 (requiring a tax to be "applied to an activity with a substantial nexus with the taxing State" to satisfy the Commerce Clause).

This Court has "more than once . . . struck down taxes directly imposed on or resulting from out-of-state sales which were held to be insufficiently related to activities within the taxing State, despite the fact that the vendor knew that the goods were destined for use in that State." *American Oil Co. v. P.G. Neil*, 380 U.S. 451, 457 (1965) (citations omitted). As with regulatory power generally in *Baldwin* and *Healy*, the Commerce Clause places a territorial limit upon the state's taxation power. *See Bellas Hess*, 386 U.S. at 759 (vendor whose only contacts with taxing state are by mail or common carrier lacks substantial nexus required by Commerce Clause).

States may require payments from out-of-state firms in connection with those firms' commercial transactions *within the state*. However, they may not collect sales taxes from out-of-state firms in connection with sales that are wholly outside of the state. The Maine Rx law exacts payments from manufacturers, even when they are not responsible for delivering their products to, and are strangers to the triggering retail sales within, the state. Indeed, it does so

even when those retail transactions involve no physical presence of the manufacturer in Maine.[9] The State thus attempts to "tax" manufacturers' out-of-state activities even where their "taxed" drug sales have no nexus at all, much less a substantial one, with the State of Maine.

When Maine exacts Maine Rx rebates on manufacturers' out-of-state transactions, merely because the drugs sold wind up crossing a pharmacy counter in Maine, the Act's rebate requirement necessarily fails the *Complete Auto* Commerce Clause test for taxes. *See Complete Auto*, 430 U.S. at 277-79; *see also Quill*, 504 U.S. at 311; *Bellas Hess*, 386 U.S. at 759; *P.G. Neil*, 380 U.S. at 457-58. This is an independently sufficient basis for this Court's review.

III. The Statutory and Constitutional Questions Are of National Importance in Light of Pending Legislation in Dozens of States

The national import of this case is easily demonstrated. In the absence of a federal-level drug benefit for the elderly, many states anxious to make prescription drugs more affordable for their citizens wait in the wings with legislation modeled on Maine Rx. They are watching this case to resolve the current conflict in the circuits regarding Medicaid's scope, and to clarify the Commerce Clause boundaries of their authority. Were this Court to decline review, it would give these dozens of states a green light to copy Maine's program, rapidly multiplying the constitutional and commercial harms that the Maine Rx

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[9] While manufacturers' other activities in Maine (advertising, direct sales that do not trigger Maine Rx rebates, *etc.*) might constitute sufficient minimum contacts with the state for Due Process purposes, they do not establish the requisite "substantial nexus" with Maine for Commerce Clause purposes in imposing a tax on manufacturers' out-of-state transactions. *See Quill*, 504 U.S. at 312-13.

program inflicts, and leading to proliferating litigation in the lower courts.

The Center for Policy Alternatives, a non-profit think tank serving state legislators, state policy organizations, and state grassroots leaders, for example, is promoting model prescription drug pricing legislation whose text is a nearly verbatim replica of the Maine Rx law—state legislatures need only fill in the blank with the state's name to create a copycat "State Rx" program.[10] By the Center's count, some 27 states have taken steps to do so.[11] The National Conference of State Legislatures reports that over 40 states are considering price-related prescription drug legislation.[12]

The proposed "Alabama Prescription Drug Fair Pricing Act" is just one such example. Like Maine's Act, it provides that drug manufacturers "shall enter into" rebate agreements, that state officials "shall obtain" rebates equal to or greater than Medicaid rebates, and that the state "shall impose prior authorization requirements in the state Medicaid program" on the drugs of manufacturers who do not pay the mandated rebates. *See* H.B. 1, 2001 Reg. Sess. (Ala. 2001). Nearly identical bills have also been introduced this year in Arkansas, Hawaii, Louisiana, Minnesota, Oregon, Pennsylvania, and Tennessee. *See* H.B.

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[10] *See* Center for Policy Alternatives, *Model Legislation: Prescription Drug Fair Pricing Act*, *at* http://www.stateaction.org/issues/healthcare/prescription/fairpricemodel.cfm.

[11] *See* Center for Policy Alternatives, *States Poised to Lower Prescription Drug Prices as First Circuit Court of Appeals Rules Against PhRMA* (May 17, 2001), *at* http://www.stateaction.org/cpa/pressroom/archives/prcomplete.cfm?ID=139.

[12] *See* National Conference of State Legislatures, *2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation*, *at* http://www.ncsl.org/programs/health/drugdisc01.htm (last modified July 24, 2001).

1925, 83rd Leg., Reg. Sess. (Ark. 2001); H.B. 47, 2001 Reg. Sess. (Haw. 2001); H.B. 1089, 2001 Reg. Sess. (La. 2001); H. 944, S. 765, 82d Leg., Spec. Sess. (Minn. 2001); S. 877, 71st Leg., Reg. Sess. (Ore. 2001); H.B. 444, 2001 Gen. Assem., Reg. Sess. (Pa. 2001); H. 123, S. 19, 102d Gen. Assem., Reg. Sess. (Tenn. 2001).[13]

The bills just described are those that most closely replicate the Maine Rx program. Many other states, however, are pursuing mandatory Maine Rx-style discounts or "rebate agreements" in other forms. Expanded access to prescription drugs is at the top of the national policy agenda, and the political and media debates fuel state initiatives like the ones above. However desirable national public policy attention to this issue may be, states may not in the meantime balkanize the national economy by regulating manufacturers' sales outside their borders, or leverage authority under the Medicaid statute to serve non-Medicaid populations.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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[13] In addition, bills in a number of state legislatures this year replicate many but not all aspects of the Maine Rx Act. *See* H.B. 5050, 2001 Gen. Assem., Jan. Sess. (Conn. 2001); H.B. 2236, 92d Gen. Assem. (Ill. 2001); H.B. 2026, 112th Gen. Assem., 1st Reg. Sess. (Ind. 2001); H.B. 2692, 2001 Gen. Assem., Reg. Sess. (Va. 2001); H.B. 1073, 57th Leg., 1st Spec. Sess. (Wash. 2001).

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July 31, 2001

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff, Appellee,
v.
KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, and MAINE ATTORNEY GENERAL,
Defendants, Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE
[Hon. D. Brock Hornby, *U.S. District Judge*]

Before
Bownes, *Senior Circuit Judge*,
Keeton and Saris*, *District Judges*.

Andrew S. Hagler, Assistant Attorney General, with whom *G. Steven Rowe*, Attorney General, *Paul Stern*, Deputy Attorney General, *John R. Brautigam*, Assistant Attorney General, *Cabanne Howard*, and *University of Maine Law School*, were on brief, for appellant.

Thomas C. Bradley, *Arn H. Person* and *Maine Citizen Leadership Fund* on brief for Viola Quirion, Michelle Campbell, Maine Council of Senior Citizens and Richard Donahue, M.D., amici curiae.

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* Of the District of Massachusetts, sitting by designation.

Kathleen M. Sullivan, with whom *Daniel M. Price, Allen S. Rugg, Marinn F. Carlson, Powell, Goldstein, Frazer & Murphy, L.L.P., Bruce C. Gerrity* and *Preti, Flaherty, Beliveau, Pachios & Haley L.L.C.,* were on brief, for appellees.

Daniel J. Popeo, Richard A. Samp and *Washington Legal Foundation,* on brief for Washington Legal Foundation, Allied Educational Foundation, International Patient Advocacy Association, Kidney Cancer Association, The Seniors Coalition, and The 60 Plus Association, amici curiae.

Steven J. Rosenbaum, David H. Remes, Covington & Burling, Robin S. Conrad and *National Chamber Litigation Center* on brief, for the Chamber of Commerce of the United States, amicus curiae.

Edwin D. Schindler on brief *pro se*, amicus curiae.

May 16, 2001

BOWNES, *Senior Circuit Judge*. In this case, we consider whether a Maine statute providing for affordable prescription drugs can survive facial constitutional challenges. On October 26, 2000, the district court issued a preliminary injunction preventing the implementation of the statute on the ground that it is preempted by the Supremacy Clause and violates the dormant Commerce Clause. We reverse.

I. BACKGROUND

On May 11, 2000, the Governor of Maine signed into law an Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S. P. 1026) (L. D. 2599)

(the "Act"), which establishes the "Maine Rx Program" (the "Program").[1]

The statute was enacted because of the Maine Legislature's concern that many Maine citizens who were not Medicaid recipients could not afford necessary prescription drugs. It is predicated on the economic reality that volume buying of prescription drugs by Medicaid administrators, insurance companies and health maintenance organizations ("HMOs") resulted in substantially lower prices for these entities than for individual purchasers. A minority staff report for the United States House Committee on Government Reform and Oversight found that the average retail price for individual elderly purchasers was 86 percent higher than the price charged to the federal government and other favored customers, such as HMOs.

The Program is open to all State residents, and allows enrollees to purchase prescription drugs from participating Maine pharmacies at a discounted price. The discount offered by the pharmacies is reimbursed by the State out of a dedicated fund created with the money raised from "rebate payments" collected from participating drug manufacturers. Me. Rev. Stat. Ann. tit. 22, § 2681. The obligation to pay the "rebate" is triggered by the retail sale of the manufacturer's drugs to a Program enrollee through a participating pharmacy.

The Act directs the Commissioner of Maine's Department of Health Services to negotiate rebate agreements with manufacturers. *Id.* § 2681(3). These rebate agreements are similar in form to the rebate agreements required of manufacturers participating in the Maine Medicaid outpatient drug program. *Id.* § 2681(4). In negotiating the rebate, the Commissioner is directed to

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[1] The full text of the relevant provisions of the Act is set forth in the Appendix, *infra*.

"consider" the rebate amount calculated under the Federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8, and to use his or her "best efforts" to obtain an initial rebate in the same amount. Me. Rev. Stat. Ann. tit. 22, § 2681(4)(A)-(C). Rebate payments are made quarterly on the basis of retail sales records for that quarter. *Id.* § 2681(3).

In order to create an incentive for manufacturers to enter rebate agreements with the Commissioner, the Act provides that names of manufacturers who do not enter into agreements be released to health care providers and the public. *Id.* § 2681(7). More importantly, the drugs of all noncompliant manufacturers are required to be subject, "as permitted by law," to the "prior authorization requirements" in the State Medicaid program. *Id.* § 2681(7). When subjected to prior authorization, a drug may not be dispensed to a Medicaid beneficiary without the approval of the State Medicaid administrator.

The plaintiff-appellee, Pharmaceutical Research & Manufacturers of America ("PhRMA"), brought an action in the United States District Court in the District of Maine against defendant-appellants Commissioner of the Maine Department of Human Services and the Maine Attorney General, challenging the constitutionality of the Act. PhRMA claimed that the Act violated the dormant Commerce Clause and was preempted by the federal Medicaid statute under the Supremacy Clause, and moved for a preliminary injunction to prevent the implementation of the Act.

The district court issued the preliminary injunction and found the Act unconstitutional on the two asserted grounds. First, the district court held that the Act had an impermissible extraterritorial reach by regulating the revenues out-of-state pharmaceutical manufacturers receive when selling to out-of state pharmaceutical distributors, thereby violating the dormant Commerce Clause. As to those distributors located in the State of Maine, the district

court held that the Act was preempted under the Supremacy Clause because it conflicted with the federal Medicaid program.[2]

II. DISCUSSION

A. Standard of Review

"The criteria for the grant of a preliminary injunction are the familiar four: likelihood of success, risk of irreparable harm, the balance of equities and the public interest." *Langlois v. Abington Hous. Auth.*, 207 F.3d 43, 47 (1st Cir. 2000) (citing *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 15 (1st Cir. 1996)). When a district court's grant of a preliminary injunction is appealed, our standard of review depends on the issue under consideration: we review pure issues of law de novo, findings of fact for clear error, and "judgment calls" with considerable deference. *Id.* (noting that our standard of review is sometimes summarized as being for "abuse of discretion").

The district court concluded that PhRMA's likelihood of success on the merits of most of its constitutional challenges was "overwhelming." Accordingly, it dealt only cursorily with the remaining preliminary injunction factors. Our review also focuses on PhRMA's likelihood of success on the merits of its challenges under the Supremacy Clause and the Commerce Clause. *See Weaver v. Henderson*, 984

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[2] The Act also contained a provision that made it "illegal profiteering" for a manufacturer to "exact[] or demand[] an unconscionable price" or to "exact[ ] or demand[ ] prices or terms that lead to any unjust or unreasonable profit." An Act to Establish Fairer Pricing for Prescription Drugs, § 2697(2), 2000 Me. Legis. Ch. 786 (S. P. 1026) (L.D. 2599) (to be codified at Me. Rev. Stat. Ann. tit. 22, § 2697(2)). The district court found this provision unconstitutional. The State of Maine has not appealed this ruling.

F.2d 11, 12 (1st Cir. 1993) (stating that the "sine qua non" of preliminary injunction analysis is whether plaintiff is likely to succeed on merits of claim).

B. Standing

The initial question we face is whether PhRMA has prudential standing to challenge the prior authorization provision of the Act. PhRMA contends that Maine's standing argument was not briefed to the district court, and therefore was waived. We assume, without deciding, that Maine may assert this standing challenge on appeal, and hold that PhRMA falls within the relevant "zone of interest."[3]

The Supreme Court recently reiterated the standard for determining prudential standing:

> [I]n applying the "zone of interests" test, we do not ask whether, in enacting the statutory provision at issue, Congress specifically intended to benefit the plaintiff. Instead, we first discern the interests "arguably . . . to be protected" by the statutory provision at issue; we then inquire whether the plaintiff's interests affected by the agency action in question are among them.

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[3] There is some dispute among the circuits as to whether prudential standing (as opposed to Article III standing) can be raised for the first time on appeal. *Compare Animal Legal Def. Fund v. Espy*, 23 F.3d 496, 499 (D.C. Cir. 1994) (prudential standing is non-waivable); *Thompson v. County of Franklin*, 15 F.3d 245, 248 (2d Cir. 1994) (same); *Cmty. First Bank v. Nat'l Credit Union Admin.*, 41 F.3d 1050, 1053 (6th Cir. 1994) (same) with *Pershing Park Villas Homeowners Ass'n v. United Pac. Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000) (prudential standing is waivable); *Lindley v. Sullivan*, 889 F.2d 124, 129 (7th Cir. 1989) (same) Because we hold that Maine's challenge to PhRMA's standing would be unsuccessful in any event, as explained *infra*, it is not necessary for us to decide the waiver issue now.

Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co., 522 U.S. 479, 492 (1998).

Maine contends that PhRMA's interest is purely financial and is limited to ensuring that its members' drugs are prescribed instead of competitors' drugs. Nothing in the Medicaid statute, Maine argues, suggests that Congress intended to protect sales of any particular drugs. *See Tap Pharms. v. U.S. Dep't of HHS*, 163 F.3d 199, 208 (4th Cir. 1998) (holding that pharmaceutical manufacturer lacked standing to challenge Medicare rules reducing reimbursement amounts paid for their products because manufacturer's financial interests were not within zone of interests protected by Medicare).

PhRMA has not asserted an action to enforce rights under the Medicaid statute, however, but rather a preemption-based challenge under the Supremacy Clause. In this type of action, it is the interests protected by the Supremacy Clause, not by the preempting statute, that are at issue. *St. Thomas-St. John Hotel & Tourism Ass'n v. Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000). As the Third Circuit recently pointed out, an entity does not need prudential standing to invoke the protection of the Supremacy Clause:

> We know of no governing authority to the effect that the federal statutory provision which allegedly preempts enforcement of local legislation by conflict must confer a right on the party that argues in favor of preemption. On the contrary, a state or territorial law can be unenforceable as preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption.

Id. Thus, regardless of whether the Medicaid statute's relevant provisions were designed to benefit PhRMA, PhRMA can invoke the statute's preemptive force. *Cf.*

Burgio & Campofelice, Inc. v. N.Y. State Dep't of Labor, 107 F.3d 1000, 1006 (2d Cir. 1997) (concluding that the Supremacy Clause creates an implied right of action for injunctive relief against state officers who are threatening to violate federal law).

Given that PhRMA has prudential standing grounded in the Supremacy Clause, we think it may fairly assert the rights of Medicaid recipients for purposes of this action. Where a party has established a concrete injury in fact, and otherwise has standing to challenge the lawfulness of the statute, it is "entitled to assert those concomitant rights of third parties that would be 'diluted or adversely affected' should [its] constitutional challenge fail and the statute[] remain in force." *Craig v. Boren*, 429 U.S. 190, 195 (1976) (quoting *Griswold v. Connecticut*, 381 U.S. 479, 481 (1965)). Accordingly, "vendors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function." *Id.*, *see also* 1 L. Tribe, *American Constitutional Law*, §3-19, p. 438 (3d ed. 2000).

C. Preemption

Having decided that PhRMA has standing to challenge the Maine Act on preemption grounds, we now turn to the merits of that argument. The district court addressed preemption only with regard to the Act's regulation of sales to in-state distributors, after concluding that such regulation would not be barred by the Commerce Clause. It held that the prior authorization review requirement of the Act, Me. Rev. Stat. Ann. tit. 22, §2681(7), conflicted with the purposes of the Medicaid program such that the requirement was invalid under the Supremacy Clause.[4] If we affirm the

[4] Only the prior authorization review requirement of the Act is at issue for preemption purposes, not the public identification requirement. Therefore, for simplicity's sake, our use of the terms "the Act" or "Maine Rx Program" refer solely to the prior authorization review requirement.

district court's preemption holding, it would invalidate the Act as to all distributors, not just those who operate in Maine, and would obviate the need to address the Commerce Clause. Therefore, we analyze the issue of preemption first.[5]

Under the Supremacy Clause, a federal law may expressly or impliedly preempt state law. U.S. Const. art. VI, cl. 2 (stating that federal law "shall be the supreme law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"). As the parties agree, only "implied conflict preemption" is at issue here.[6]

[5] An amicus curiae brief offers another basis for federal preemption: Edwin D. Schindler, Major Stockholder and Patent Attorney, argues that the Maine Act is preempted by federal patent law. Because these issues were raised for the first time on appeal by an amicus, not by a party, we do not consider them. *Am. Fed'n of Gov't Employees, Local 3936 v. Fed. Labor Relations Auth.*, 239 F.3d 66, 69 (1st Cir. 2001); *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 6 (1st Cir. 1996) ("an amicus cannot introduce a new argument into a case").

[6] Express preemption of a state law occurs where "a federal statute explicitly confirms Congress's intention to preempt state law and defines the extent of that preclusion." *Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 15 (1st Cir. 2000). There is no explicit language in the Medicaid statute that forbids the Maine Rx Program. Nor is the doctrine of "field" preemption relevant, as Medicaid is a cooperative federal and state program. This form of implied preemption applies only when a federal regulatory scheme is so pervasive as to create the inference that Congress did not intend for the states to pass supplemental law in that area. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). Therefore, we

Our task, therefore, is to consider if "compliance with both state and federal regulations is impossible" or if "state law interposes an obstacle to the achievement of Congress's discernable objectives." *Grant's Dairy-Me., LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res.*, 232 F.3d 8, 15 (1st Cir. 2000) (citing *Gade v. v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992)).

In doing so, we assume "that the historic police powers of the States [are] not to be superceded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *Id.* at 14-15 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). We also recognize that federal preemption of a state law is "strong medicine," and is "not casually to be dispensed." *Id.* at 18. This is especially true when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism": "Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one." *Wash., Dep't of Soc. & Health Servs. v. Bowen*, 815 F.2d 549, 557 (9th Cir. 1987) (quoting *N. Y. Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 421 (1973)).

To determine whether the state regulation is consistent with the federal statute, we examine the "structure and purpose of the [federal] statute as a whole." *Gade*, 505 U.S. at 98. The primary purpose of Medicaid is to enable states to provide medical services to those whose "income and resources are insufficient to meet the costs of necessary medical services . . . ." 42 U.S.C. §1396 (2000). Congress expressly intended that the provision of medical services be administered by the state "in a manner consistent with

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consider only implied conflict preemption as a basis for PhRMA's argument.

simplicity of administration and the best interests of the recipients." *Id.* § 1396a(a)(19).

We perceive no conflict between the Maine Act and Medicaid's structure and purpose. Neither the letter nor the intent of the Medicaid statute prevents states from imposing prior authorization requirements; indeed, they are explicitly permitted. 42 U.S.C. § 1396r-8(d)(1)(A) (states may "subject to prior authorization any covered outpatient drug"). The statute sets forth only two limitations on a state's use of prior authorization: the state must provide "response by telephone or other telecommunication device within 24 hours of a request for prior authorization;" and, with respect to most drugs, provide for "the dispensing of at least 72-hour [sic] supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary)." *Id.* § 1396r-8(d)(5)(A) and (B).

The plain text of the Maine Act appears to incorporate these Medicaid requirements. It provides: "The department shall impose prior authorization requirements in the Medicaid program under this Title, *as permitted by law*, for the dispensing of prescription drugs . . . ." Me. Rev. Stat. Ann. tit. 22, § 2681(7) (emphasis added). We read the language "as permitted by law" to limit the Act's application to only those situations in which prior authorization is permitted by Medicaid.[7] As the Department is charged with administering the Maine Rx Program, we owe deference to its interpretation of the Act. *Fireside Nissan, Inc. v. Fanning*, 30 F.3d 206, 212 (1st Cir. 1994).

Moreover, as set forth in the affidavit of Kevin Concannon, Commissioner of the Maine Department of

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[7] Kevin Concannon, Commissioner of the Maine Department of Human Services, affirms in an affidavit that the Department will not impose prior authorization that would conflict with the Medicaid requirements.

Human Services, Maine has proposed administrative rules governing prior authorization aimed at ensuring that Medicaid recipients will have access to needed medications. Specifically, the decision to place a drug on the prior authorization list may be made only by the State's Medicaid Drug Utilization Review [DUR] Committee, which exclusively comprises physicians and pharmacists licensed to prescribe or dispense medications in Maine. Concannon states:

> In making its determination of whether or not a prior authorization requirement is clinically appropriate, the DUR Committee shall be guided by the law of Medicaid, and particularly the principle that Medicaid recipients shall be assured access to all medically necessary prescription drugs.

PhRMA contends that prior authorization, however implemented, necessarily interferes with the delivery of Medicaid services by placing an administrative burden on physicians and patients. This interference is acceptable, it says, when performed in the usual course of the Medicaid regulations concerning prior authorization, 42 U.S.C. § 1396r-8(d)(5), because there is a countervailing "legitimate" purpose of preventing abuse or over-prescription of certain expensive medications. In the case of a prior authorization under the Maine Rx Program, however, PhRMA argues (and the district court agreed) that there is no "Medicaid purpose" or "benefit" to Medicaid that offsets the interference. Hence, it contends, only when a prior authorization is motivated by the refusal to enter into a Maine Rx Program rebate agreement is it preempted.

This argument is unpersuasive. First, we are not convinced that the Medicaid statute is concerned with the motivation behind imposing prior authorization, as long as the 24-hour response and the 72-hour drug-supply requirements, 42 U.S.C. § 1396r-8(d)(5), are satisfied.

Thus, even if the district court's conclusion that "Maine can point to no Medicaid purpose in this new prior authorization requirement" is true, it does not necessarily mean that the prior authorization scheme *conflicts* with the objectives of the Medicaid program. We see no basis for inflicting the "strong medicine" of preemption on a state statute that, in the absence of an actual conflict, merely fails to directly advance the purpose of the federal program.

Moreover, even assuming that this inquiry into the underlying objectives of the Act is appropriate, we disagree that the Act serves no purpose related to Medicaid. The purposes of the Medicaid statute, read broadly, are consonant with the purposes of the Maine Rx Program. First, the Maine Rx Program furthers Medicaid's aim of providing medical services to those whose "income and resources are insufficient to meet the costs of necessary medical services," 42 U.S.C. § 1396, even if the individuals covered by the Maine Rx Program are not poor enough to qualify for Medicaid. Second, there is some evidence in the record that by making prescription drugs more accessible to the uninsured, Maine may reduce Medicaid expenditures. When people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible. *See* Stephen B. Soumerai, Sc.D., Dennis Ross-Degnan, Sc.D., *Inadequate Prescription-Drug Coverage for Medicare Enrollees - A Call to Action,* New England Journal of Medicine, Vol. 340, No. 9, March 4, 1999 (contained in district court record); Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans,* Committee on Government Reform and

Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, October 9, 1998 (same).[8]

Thus, we disagree with the district court's statement that "If Maine can use its authority over Medicaid authorization to leverage drug manufacturer rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into a state program for highway and bridge construction or school funding." Neither highway construction nor school funding relate in any way to the purposes of providing medical services to the needy, *see* 42 U.S.C. § 1396, or of cost effective administration of the Medicaid program, *see id.* § 1396a(a)30(A) (state plans must assure that payments are consistent with, inter alia, efficiency and economy).

PhRMA further contends that the Maine Rx Program will necessarily harm Medicaid recipients by impeding access to their doctors' first-choice medications. The district court agreed with this argument, concluding that the Maine Act conflicted with the Medicaid provision setting forth a general requirement that a state Medicaid plan contain safeguards to assure that care and services will be provided "in a manner consistent with . . . the best interests of the recipients." 42 U.S.C. § 1396a(a)(19). PhRMA vigorously presses the argument that the prior authorization provision is more than a *de minimus* obstacle to achieving these best interests of the Medicaid recipient because it will effectively require a doctor to shift to her second choice drug where the first choice drug is manufactured by a

[8] Moreover, the Amicus Curiae Brief of Viola Quirion, Michelle Campbell, Maine Council of Senior Citizens and Richard Donahue, M. D. attaches an affidavit from Maine resident Viola Quirion indicating that because many older persons cannot afford the high costs of prescription drugs, there may be increased enrollment in nursing homes and an increased burden on Medicaid.

company that does not participate in the rebate program. The state concedes that it will not authorize payment for the first-choice drug manufactured by a non-participant where there is another drug for the ailment manufactured by a participant, but insists that the Medicaid recipient will always receive medically necessary drugs. At this point in the proceedings, we find insufficient basis for concluding that the Maine Act, on its face, controverts the Medicaid goal of "best interests."

Because this is a facial challenge to a statute, PhRMA has a difficult burden of showing that Medicaid recipients will be harmed by the Maine Rx Program. "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *United v. Salerno,* 481 U.S. 739, 745 (1987). "The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute." *Rice v. Norman Williams Co.,* 458 U.S. 654, 659 (1982).

Here, the parties submitted competing affidavits discussing whether the Maine Rx Program will necessarily inflict harm on Medicaid patients. Dr. Scott Howell, Vice President of National Accounts, Managed Care, SmithKline Beecham Corporation, states that "when used wrongly," prior authorizations hurt medical professionals and patients by adding administrative burdens, delays, anxiety and confusion. He opines that the Maine Rx Program "will create a high likelihood" of harm by leading to inappropriate prescribing of medications, needlessly burdening doctors, and causing unnecessary inconvenience for Medicaid recipients. "[P]rior authorization of drugs, without regard to safety or efficacy, will lead to drugs being prescribed that are less safe and efficacious."

Dr. Timothy S. Clifford, the Medical Director for the Maine Bureau of Medical Services, which administers the

Medicaid program, disagrees with Dr. Howell's affidavit on several points. He contends that the Department will address safety and efficacy concerns in administering the Maine Rx Program's prior authorization requirement; that it will consider the availability of alternative drugs in deciding whether to subject a particular drug to the requirement; and that Medicaid recipients will continue to have access to medically necessary drugs. Dr. Clifford states: "The Department certainly will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturer participates in the Maine Rx Program . . . ."

Dr. H. Burtt Richardson, Jr., a Maine pediatrician and Maine Medicaid provider, states that he supports the Maine Rx Program "so long as the decision to put a prior authorization on particular drugs is clinically appropriate, feasible for a medical office, and accompanied by the assurance that all Maine Medicaid recipients have access to medically necessary drugs."

These affidavits, along with other materials in the record, fall short of establishing that the Act will inflict inevitable or even probable harm on Medicaid patients or their providers. In reviewing a preemption-based facial challenge, "we do not rest our decision on consequences that, while possible, are by no means predictable." *Dep't of Taxation and Fin. of N.Y. v. Milhelm Attea & Bros., Inc.*, 512 U.S. 61, 69 (1994). There is no evidence that the prior authorization procedure is likely to foreclose a patient from receiving a necessary drug. Although prior authorization review is triggered by a manufacturer's refusal to participate in the Maine Rx Program, the record indicates that the final decision to require prior authorization for a particular drug is based primarily on clinical criteria applied by health care professionals.

Since both sides agree that the prior authorization requirement is the "hammer" or "force" that coerces

manufacturers to enter into the Program, the possibility that first-choice drugs will not be readily approved where second-choice inferior alternatives exist concerns us. The possibility that the administrative implications of the prior authorization requirement will affect the quality of medical care for Medicaid recipients in more subtle ways, i.e. through inconveniencing prescribing physicians, also concerns us. Dr. Howell's affidavit, however, is controverted by the affidavits of other qualified individuals. We simply cannot say on this record that the Act conflicts with Medicaid's requirement that state Medicaid plans assure that care will be provided in a manner consistent with the recipients' best interests. 42 U.S.C. § 1396a(a)(19).

This decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement "as applied." *See United States v. Hilton,* 167 F.3d 61, 71 (1st Cir.), *cert. denied*, 528 U.S. 844 (1999) ("It makes little sense to strike down an entire statute in response to a facial attack when potential difficulties can be remedied in future cases through fact-specific as-applied challenges."); *see also Corgain v. Miller,* 708 F.2d 1241, 1251 (7th Cir. 1983) (upholding facial adequacy of plan for prisoner's access to law library, but not foreclosing future challenge to plan as implemented).

D. Dormant Commerce Clause

Holding that the Maine Act is not preempted by the Medicaid statute, we next consider whether it violates the dormant Commerce Clause. The Constitution provides that Congress shall have the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes[.]" U.S Const. art. I, § 8, cl. 3. The constitutional provision affirmatively granting Congress the authority to legislate in the area of interstate commerce "has long been understood, as well, to provide 'protection from

state legislation inimical to the national commerce [even] where Congress has not acted. . . . "" *Nat'l Foreign Trade Council v. Natsios,* 181 F.3d 38, 61 (1st Cir. 1999) (alterations in original) (quoting *Barclays Bank PLC v. Franchise Tax Bd. of Cal.,* 512 U.S. 298, 310 (1994)), *aff'd sub nom. Crosby v. Nat'l Foreign Trade Council,* 530 U.S. 363 (2000). This negative command, known as the dormant Commerce Clause, prohibits states from acting in a manner that burdens the flow of interstate commerce. *Okla. Tax Comm'n v. Jefferson Lines, Inc.,* 514 U.S. 175, 179-80 (1995); *Healy v. Beer Inst.,* 491 U.S. 324, 326 n.1 (1989).

The restriction imposed on states by the dormant Commerce Clause is not absolute, and "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor,* 477 U.S. 131, 138 (1986) (internal quotation marks omitted). The prohibitions imposed upon state regulation by the dormant Commerce Clause have fallen into several identifiable categories. To determine whether a statute violates the dormant Commerce Clause, we apply one of several levels of analysis, depending on the effect and reach of the legislation.

First, a state statute is a per se violation of the Commerce Clause when it has an "extraterritorial reach." *Healy,* 491 U.S. at 336. "[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.* When a state statute regulates commerce wholly outside the state's borders or when the statute has a practical effect of controlling conduct outside of the state, the statute will be invalid under the dormant Commerce Clause. *Cotto Waxo Co. v. Williams,* 46 F.3d 790, 793 (8th Cir. 1995) (citing *Healy*). A statute will have an extraterritorial reach if it

"necessarily requires out-of-state commerce to be conducted according to in-state terms." *Id.* at 794.

Second, if a state statute discriminates against interstate commerce, we apply strict scrutiny. It will be scrutinized under a "virtually per se invalid rule," which means that the statute will be invalid unless the state can "show that it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives." *Or. Waste Sys.. Inc. v. Dep't of Envtl. Quality of Or.,* 511 U.S. 93, 100-01 (1994) (alteration and internal quotation marks omitted). This level of scrutiny will be applied if the state statute discriminates against interstate commerce on its face or in practical effect. *Taylor,* 477 U.S. at 138; *see also Bacchus Imports, Ltd. v. Dias,* 468 U.S. 263, 270 (1984) (indicating that a finding of discriminatory purpose or discriminatory effect can constitute economic protectionism subjecting the state statute to a "stricter level of invalidity"). When a state statute "discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, we have generally struck down the statute without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.,* 476 U.S. 573, 579 (1986).

Third, a lower standard of scrutiny is applied when the state statute regulates evenhandedly and has only incidental effects on interstate commerce. In this situation, a balancing test is applied. *Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142 (1970). "Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.*

PhRMA contends that the Maine Act is an impermissible exercise in extraterritorial regulation and, therefore, is per se violative of the dormant Commerce Clause. It argues that the Act necessarily regulates the

transaction that occurs between the manufacturer and the distributor outside the borders of Maine.

Maine first argues that we need not reach the issue of whether the Act violates the dormant Commerce Clause because it is acting as a "market participant" and is therefore exempt from Commerce Clause restrictions.[9] *See South-Central Timber Dev., Inc. v. Wunnicke,* 467 U.S. 82, 93 (1984) ("if a State is acting as a market participant, rather than as a market regulator, the dormant Commerce Clause places no limitation on its activities"). We hold that Maine does not fall under the market participant exception to the dormant Commerce Clause. Maine is not a market buyer of prescription drugs, except as required by the Medicaid statute. Its citizens will continue to directly purchase prescription drugs as needed. Nothing in the Act makes Maine a market participant.

Maine alternatively argues that the Act evenhandedly regulates in-state conduct that only has an incidental effect on interstate commerce. Maine contends that we should apply the lower level of scrutiny, use the *Pike* balancing test, and find that the local benefits of the Maine Rx Program outweigh the incidental burden on interstate commerce.

The Maine Act represents a novel legislative approach to one of the serious problems of our time, one that resists easy analysis. We address each of the potentially applicable dormant Commerce Clause prohibitions to determine the appropriate analysis and level of scrutiny.

1. Per Se Invalidity: Extraterritorial Reach

A state may not pass laws that have the "practical effect" of regulating commerce occurring wholly outside

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[9] *See* Judge Lynch's opinion in *Nat'l Foreign Trade Council,* 181 F.3d at 62-65, for a thorough scholarly discussion of a state as a market participant.

that State's borders . . . ." *Healy,* 491 U.S. at 332. When evaluating the practical effect of the statute, the court should consider the statute itself, and "how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." *Id.* at 336.

PhRMA relies on three cases to support its argument that the Maine Act is per se invalid because it regulates conduct beyond the borders of Maine. The cases cited, however, are inapposite to the facial construction of the Maine Act. PhRMA construes these cases as standing for the proposition that, "a state may not dictate the terms on which buyers and sellers do business outside of the state." *See, e.g., Healy,* 491 U.S. at 338; *Brown-Forman,* 476 U.S. at 583-84. This is partially correct but does not reflect the entire picture. The cases on which PhRMA relies, however, involve price control, price affirmation or price tying schemes. *See Healy,* 491 U.S. at 326; *Brown-Forman,* 476 U.S. at 575-76; *Baldwin v. G.A.F. Seelig,* 294 U.S. 511, 519 (1935) ("*Seelig*"). The statutes in these cases involved regulating the prices charged in the home state and those charged in other states in order to benefit the buyers and sellers in the home state, resulting in a direct burden on the buyers and sellers in the other states.

In *Healy*, the Court struck down a Connecticut Liquor Control Act that required out-of-state shippers of beer to affirm that the prices at which the products were sold to Connecticut wholesalers were no higher than prices at which those same products were sold in bordering states. 491 U.S. at 326. The Court held the statute to be unconstitutional because it controlled prices in neighboring states and interfered with the regulatory schemes in those states. *Id.* at 338-39.

In *Brown-Forman,* the Court struck down a provision of the New York Alcoholic Beverage Control Law that required liquor distillers to affirm that their prices were no

higher than the lowest price at which the same product would be sold in any other state during the month. 476 U.S. at 575-76. The Court determined that this was an extraterritorial reach violative of the Constitution. It held that "[o]nce a distiller has posted prices in New York, it is not free to change its prices elsewhere in the United States during the relevant month. Forcing a merchant to seek regulatory approval in one State before undertaking a transaction in another directly regulates interstate commerce." *Id.* at 582 (footnote omitted).

In *Seelig,* the Court struck down the New York Milk Control Act, which set minimum prices for milk purchased from in-state and out-of-state producers and banned the resale of milk in New York when that milk had been purchased out-of-state for a lower price. 294 U.S. at 519. By requiring New York wholesalers to buy out-of-state milk at certain prices, the effect of the statute was to essentially set out-of-state milk prices. The Court recognized that the Commerce Clause does not permit a state to create a "scale of prices for use in other states, and to bar the sale of products . . . unless the scale has been observed." *Id.* at 528.

The Maine Act is different from these statutes. Unlike these price affirmation and price control statutes, the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price.[10] Similarly, Maine is not tying the price of its in-state products to out-of-state prices. There is nothing within the Act that requires the rebate to be a certain amount dependent on the price of prescription drugs in other states. The Act merely says that the Commissioner of the Maine Department of Human

[10] As noted above, *supra* fn.2, the anti-profiteering provision of the Act was held unconstitutional and is not part of this appeal.

Services shall use "best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program . . . ." Me. Rev. Stat. Ann. tit. 22, § 2681(4)(B). Furthermore, unlike *Brown-Forman* and *Seelig,* the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state.

PhRMA argues strenuously that the effect of the Act will be to regulate the transaction that occurs between the manufacturer and the wholesaler -- a transaction that occurs entirely out of state. It argues that as a result of the rebate provision, manufacturers will lose a portion of their profits otherwise obtained from distributors. Admittedly, it is possible that the rebate provisions of the statute may decrease the profits of manufacturers. Simply because the manufacturers' profits might be negatively affected by the Maine Act, however, does not necessarily mean that the Maine Act is regulating those profits.

The Act does not regulate the transaction between manufacturers and wholesalers. It provides for a negotiated rebate agreement between "[a] drug manufacturer or labeler that sells prescription drugs in [Maine] through the elderly low-cost drug program . . . or any other publicly supported pharmaceutical assistance program . . . ." Me. Rev. Stat. Ann. tit. 22, § 2681(3). The rebate program is voluntary and either the manufacturer or the State may withdraw at any time with sixty days' notice. The Act directs the commissioner to "use the commissioner's best efforts" to negotiate the amount of the rebate required from the manufacturer. *Id.* § 2681(4)(B). We note that the commissioner's "best efforts" may become coercive or otherwise inappropriate, but we cannot say so on this facial challenge. This may be an issue that needs to be revisited once the Act takes effect. On a facial challenge, however, the use of the commissioner's "best efforts" indicates that the Act is not "regulating" prices, but merely "negotiating" rebates.

The Act clearly does not interfere with regulatory schemes in other states. Ultimately, the Maine Act simply regulates activity that occurs in state: (1) the purchase of the prescription drugs that triggers the rebate; (2) the negotiation of a rebate amount; and (3) the State's action subjecting a manufacturer's drug to prior authorization and releasing the manufacturer's name to health care providers and the public occurs in state. Because the regulation only applies to in-state activities, there is no extraterritorial reach and the Act is not per se invalid under the Commerce Clause.

One final consideration is the consequence of other states passing similar statutes. *See Healy*, 491 U.S. at 336 (considering "what effect would arise if not one, but many or every, State adopted similar legislation"). The most apparent effect of similar statutes being passed in other states would be a loss in profits for manufacturers. It does not appear, and PhRMA does not argue, that statutes similar to the Maine Act, if enacted, would result in manufacturers having inconsistent obligations to states, or in creating a "price gridlock" linking prices in some states to the prices in other states. *See Healy*, 491 U.S. at 340. Therefore, at this time, when we are dealing with a facial challenge to the Act, there is no evidence that adverse effects on interstate commerce will occur if such legislation were passed in other states. The Act is not per se violative of the Commerce Clause.

2. Strict Level of Scrutiny: Discriminatory Statute

A statute enacted for a discriminatory purpose is subject to strict scrutiny. *See Bacchus Imports, Ltd.*, 468 U.S. at 270. Under this strict scrutiny analysis, a statute violates the Commerce Clause unless the state can show that the statute serves a legitimate local purpose that is unrelated to economic protectionism and that the same purpose could not be achieved by nondiscriminatory means. *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979). PhRMA does not

contend, nor did the district court find, that the Maine Act discriminates on its face or in its effects. Therefore, we need not discuss it further.

3. Low Level of Scrutiny: Pike Balancing Test

When a state statute regulates evenhandedly and has only incidental effects on interstate commerce, that statute will be upheld unless the burden on interstate commerce is "clearly excessive in relation to the putative local benefits." *Pike*, 397 U.S. at 142.

> Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities. Occasionally the Court has candidly undertaken a balancing approach in resolving these issues, but more frequently it has spoken in terms of "direct" and "indirect" effects and burdens.

Id. (internal citations omitted). The Maine Act is neither an impermissible extraterritorial reach nor is it discriminatory; rather, it regulates evenhandedly and only has incidental effects on interstate commerce. Therefore, we apply this lower level of scrutiny, known as the *Pike* balancing test.

The district court found the Maine Act to be per se invalid, and therefore never determined whether it survives the *Pike* balancing test. Though the district court did not undertake such an analysis, we may conduct the *Pike* balancing test for the first time on appeal. *See Instructional*

Sys., Inc. v. Computer Curriculum Corp., 35 F.3d 813, 826 (3d Cir. 1994). In *Instructional Systems*, the Third Circuit considered a facial challenge to the New Jersey Franchise Practices Act after the district court had declared the statute per se invalid under the dormant Commerce Clause. *Id.* at 826. The court found that the statute, from a facial standpoint, survived the *Pike* test, and reversed the district court judgment which had declared the statute unconstitutional. *Id.* at 827. The Third Circuit recognized, however, that the issue of whether the statute, when applied, burdens interstate commerce could not be resolved as a matter of law. *Id.*

Applying the *Pike* balancing test to the Maine Act, we consider: (1) the nature of the putative local benefits advanced by the statute; (2) the burden the statute places on interstate commerce; and (3) whether the burden is "clearly excessive" as compared to the putative local benefits. *See Pike*, 397 U.S. at 142.

Arguably, the only burden imposed on interstate commerce by the Maine Act is its possible effects on the profits of the individual manufacturers. As the Third Circuit stated, however, "the fact that a law may have 'devastating economic consequences' on a particular interstate firm is not sufficient to rise to a Commerce Clause burden." *Instructional Sys.*, 35 F.3d at 827 (quoting *Ford Motor Co. v. Ins. Comm'r*, 874 F.2d 926, 943 (3d Cir. 1989)); *see also Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127-28 (1978) (stating that "the [Commerce] Clause protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations.").

We next consider the local benefits of the Act, which we find to be substantial. The Maine Rx Program will potentially provide prescription drugs to Maine citizens who could not otherwise afford them. The Maine Legislature has decided that without the Maine Rx Program, needy Maine citizens will continue to be deprived of necessary medical

care because of rising prescription drug costs. When measuring manufacturers' possible loss of profits against the increased access to prescription drugs for Maine citizens, the local benefits appear to outweigh the burden on interstate commerce. At the very least, the burden on interstate commerce is not "clearly excessive" as compared to the local benefits.

It is necessary to recognize the difficulty in foreseeing what events actually will occur from the enforcement of this Act, which admittedly makes the *Pike* balancing test more challenging to apply. We are forced to balance the *possible* effects, instead of the *actual* effects of the statute in action. For now, it is enough to say that the Act survives the facial challenge under the dormant Commerce Clause.[11]

E. Remaining Preliminary Injunction Factors

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[11] On appeal, Maine argues in the alternative that the Act does not violate the dormant Commerce Clause because if the rebate provision of the Act is construed as a tax, it satisfies the requirements set forth in the *Complete Auto* line of cases dealing with taxation on interstate commerce. *See Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274, 279 (1977) (holding that a state's tax on interstate commerce will be upheld only if it "is applied to an activity with a substantial nexus with the taxing State, is fairly apportioned, does not discriminate against interstate commerce, and is fairly related to the services provided by the State."). PhRMA replies, arguing that the *Complete Auto* test is not satisfied. We need not address this argument on the merits, however, because this legal theory was not raised before the district court. "'If any principle is settled in this circuit, it is that, absent the most extraordinary circumstances, legal theories not raised squarely in the lower court cannot be broached for the first time on appeal.'" *Boateng v. Interamerican Univ., Inc.*, 210 F.3d 56, 62 (1st Cir. 2000) (quoting *Teamsters Union, Local No. 59 v. Superline Transp. Co.*, 953 F.2d 17, 21 (1st Cir. 1992)). This is not one of those extraordinary circumstances.

Having concluded that PhRMA is not likely to succeed on the merits of its constitutional challenges, we need not delve into the three remaining preliminary injunction factors (risk of irreparable harm, the balance of equities and the public interest). This court has recognized that the "sine qua non" of the preliminary injunction analysis is whether the plaintiff is likely to succeed on the merits of the claim. *Weaver v. Henderson,* 984 F.2d 11, 12, 14 n.5 (1st Cir. 1993) (concluding that, after determining that there was no likelihood of success on the merits, it was not necessary to examine the other factors). We must conclude that PhRMA has not satisfied its burden to obtain a preliminary injunction preventing the implementation of the Act.

III. CONCLUSION

In this facial challenge, we perceive no conflict between the Maine Act and the Medicaid statute that would result in federal preemption. The Act sets forth prior authorization procedures that are consistent with those explicitly permitted by Medicaid. PhRMA has not established at this point that the administrative burden imposed by prior authorization will likely harm Medicaid recipients. In the absence of such evidence, we cannot conclude that the Act violates the Supremacy Clause.

Nor does the Act offend the dormant Commerce Clause. It is not an extraterritorial regulation on interstate commerce because it does not regulate conduct occurring outside the state, but only regulates in-state activities. Moreover, from a facial standpoint, the local benefits of the Act appear to outweigh any incidental burden on interstate commerce. For the reasons stated, the Maine Act survives the facial dormant Commerce Clause challenge.

This is a close case but we do not think that, under the applicable law, the State of Maine should be prohibited from putting the Act into play. We heed the dissent of Justice

Louis Brandeis in *New State Ice Co. v. Liebmann,* 285 U.S. 262, 310 (1932):

> To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country. This Court has the power to prevent an experiment. We may strike down the statute which embodies it on the ground that, in our opinion, the measure is arbitrary, capricious, or unreasonable. We have power to do this, because the due process clause has been held by the Court applicable to matters of substantive law as well as to matters of procedure. But, in the exercise of this high power, we must be ever on our guard, lest we erect our prejudices into legal principles. If we would guide by the light of reason, we must let our minds be bold.

(footnote omitted).

The decision of the district court is REVERSED and the temporary injunction is VACATED.

- Concurring Opinion Follows -

APPENDIX

The relevant provisions of the Act are as follows:

> The Maine Rx Program, referred to in this subchapter as the "program," is established to reduce prescription drug prices for residents of the

State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

* * * *

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section 254 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

A. The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

KEETON, *District Judge* (concurring).

I. Introduction

I concur in the judgment reversing the decision of the district court and vacating the preliminary injunction. Because the appropriate grounds of the decision involve issues that are fundamental to harmonizing interests in liberty and order under the Constitution of the United States, I conclude that it is appropriate, if not obligatory, that I state in a concurring opinion the grounds as I see them for reaching this judgment.

For reasons associated with undisputed facts about Pharmaceutical Benefit Managers (PBMs) and relationships between interests they represent and interests of citizens of Maine represented by the Commissioner, Maine Department of Human Services, Maine's Legislature, and Maine's Attorney General, I turn first to a more extended recitation of background facts regarding standing and jurisdiction than

appears in the opinion of the Court of Appeals, delivered by Judge Bownes.

II. Background Facts on Standing and Jurisdiction to Consider Group or Association Contentions

Did the district court have authority, and does the Court of Appeals have authority, to consider positions stated in briefs on behalf of groups or associations seeking to represent the interests of their members that they claim are materially affected by orders made, or that might be made, in the district court and on appeal?

The case before us is styled Pharmaceutical Research and Manufacturers of America, Plaintiff, Appellee, v. Kevin Concannon, Commissioner, Maine Department of Human Services, and Maine Attorney General, Defendants, Appellants.

Plaintiff/Appellee's CORPORATE DISCLOSURE STATEMENT says that "plaintiff/appellee, Pharmaceutical Research and Manufacturers of America, by and through its undersigned counsel, and, pursuant to Fed. R. Civ. P. 26.1, states that it has no parent company and that no publicly held company owns any of its stock."

In its brief, which uses the short title PhRMA to designate itself, Plaintiff/Appellee refers to additional characteristics and rights of PhRMA.

+ It has the ability to challenge adverse treatment under the Maine Act, including a challenge on preemption grounds. Plaintiff/Appellee's Brief at 34.
+ It has members who are "regulated by and make payments consistent with the provisions of the Medicaid prescription drug program." *Id.* at 36 n.21.

Also, on the basis of the limited information available in the record, I infer that some of PhRMA's members are

Pharmacy Benefit Managers (PBMs). No party or amicus, or attorney for a party or amicus, has called attention to any case explicitly declaring that PBMs have standing and a United States district court has jurisdiction to consider either a facial challenge or an as-applied challenge by a PBM to a state statute like Maine's Act to Establish Fairer Pricing for Prescription Drugs, and I am aware of none. Treating the issue as one of first impression, I would recognize both standing and jurisdiction, in the United States District Court for the District of Maine, and on appeal. In the world outside the court system, as a pragmatic matter no other person or entity is as active and effective in protecting benefits and beneficiaries of availability of pharmacy products at reasonable cost as PBMs. It is entirely appropriate in these circumstances that the standing of PBMs be recognized in United States district courts and on appeal from adjudications interpreting and applying state legislation affecting the benefits and interests of beneficiaries of marketing of pharmacy products. As the Court of Appeals for the First Circuit has previously stated, "Article III standing is largely . . . albeit not entirely . . . a practical jurisprudence." *New Hampshire Hemp Council v. Marshall,* 203 F.3d 1, 4 (1st Cir. 2000) (citing 13 Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure §3531.1, at 352, 362-63 (2d ed. 1984)).

The basis for the foregoing conclusions is a principled proposition that applies broadly. I state explicitly, for the sake of clarity, that in my view it applies to each of the following contentions, in addition to the standing of PhRMA and the standing of PBMs to make the contention stated above:

(A) claims of violation of the Supremacy Clause;

(B) claims of violation of Dormant Commerce Clause jurisprudence (as to which, with respect to PhRMA's

standing, see also Part 1I. D of opinion of the Court of Appeals, delivered by Judge Bownes).

For the reasons explained in the remainder of this opinion concurring in the judgment, I would allow standing and jurisdiction but reject on the merits other specific challenges to the Maine Rx Program.

III. Madisonian Influences on Allocation of Legislative Power in the American Legal System

The roles of state legislatures and the Congress of the United States in the American legal system owe much to James Madison's seminal thinking expressed publicly and privately during debates over the structure of the new form of federalism to be established under a constitution drafted in May, 1787 to cure deficiencies in the Articles of Confederation of 1777. *See generally* John P. Kaminski, Ph.D., Director, and Richard Leffler, Ph.D., Co-Director, The Center for Study of the American Constitution, The University of Wisconsin-Madison (Wisconsin Study), *The Origins of the Three Branches of Government,* Federal Judicial Center Traveling Seminar 3-9 (2001).

Madison, a Virginian, writing to Edmund Randolph of New York on 8 April 1787, mused:

> I hold it for a fundamental point that an individual independence of the States, is utterly irreconcilable with the idea of an aggregate sovereignty. I think at the same time that a consolidation of the States into one simple republic is not less unattainable than it would be inexpedient. Let it be tried then whether any middle ground can be taken which will at once support a due supremacy of the national authority, and leave in force the local authorities so far as they can be subordinately useful.
>
> * * * *

> Let the national Government be armed with a positive & compleat authority in all cases where uniform measures are necessary. As in trade &c. &c. Let it also retain the powers which it now possesses.
>
> Let it have a negative in all cases whatsoever on the Legislative Acts of the States as the K. of G. B. heretofore had. This I conceive to be essential and the least possible abridgement of the State Soveriegnties. Without such a defensive power, every positive power that can be given on paper will be unavailing. . . .
>
> Let this national supremacy be extended also to the Judiciary departmt. If the judges in the last resort depend on the States & are bound by their oaths to them and not to the Union, the intention of the law and the interests of the nation may be defeated by the obsequiousness of the Tribunals to the policy or prejudices of the States. It seems at least essential that an appeal should lie to some national tribunals on all cases which concern foreigners, or inhabitants of other States. . . .
>
> The supremacy of the whole in the Executive department seems liable to some difficulty. Perhaps an extension of it to the case of the Militia may be necessary and sufficient.
>
> A Government formed of such extensive powers ought to be well organized. . . .
>
> * * * *
>
> To give the new system its proper energy it will be desirable to have it ratified by the authority of the people, and not merely by that of the Legislatures.

The Origins of the Three Branches of Government, id., at 4-5. Madison concluded these thoughts with a statement that,

fearing "you will think this project, if not extravagant, absolutely unattainable and unworthy of being attempted," he conceived it "to go no further than is essential." *Id.* at 6.

In his Notes of Convention Debates, Madison records Resolutions proposed by Mr. Randolph in Convention on May 29, 1787, including a set of proposals for a form of federalism remarkably similar to Madison's suggestions six weeks earlier.

Those Madisonian suggestions are reminders of two salient points relevant to our consideration of the issues presented in the present appeal.

First. The genius of the Constitution of the United States of America is that it establishes a unique form of federalism, unlike any ever fashioned before, that harmonizes and accommodates in new and distinctive ways national and state centers of governmental power.

Second. The authority for this new form of federalism is declared by "the people, and not merely by the Legislatures." *See id* at 5.

The eighteenth-century debates in which Madison and Randolph were among the key participants occurred more than two centuries ago. Twenty-first century readers are even more removed than the lapse of time suggests from being in tune with the spirit and culture surrounding the debates over what became the Constitution of the United States and the Bill of Rights embodied in the Amendments adopted forthwith. Those debates were strikingly lively and thorough examinations of the history of peoples' ideas and efforts to form governments powerful enough to preserve the order essential to protection of individual liberty and at the same time subject to inherent controls against abuse of power likely to lead to despotism.

Ideas about liberty and order are no less relevant now than they were when the Founders developed the Constitution of the United States of America. "The aim of

the American legal system is liberty and justice for all. How close we come to that aim depends on good judging." Robert E. Keeton, *Judging in the American Legal System* 1 (Lexis Law Publishing 1999).

> The quality of judging in a legal system depends on commitment. It depends, first, on commitment to the aim of justice. Second, it depends on commitment to professionalism. The declared beliefs of all professionals in the system - including advocates, counselors, and academic critics as well as judges -affect the quality of judging in the system. Third, the quality of judging depends on commitment to method. Judicial choice, at its best, is reasoned choice, candidly explained.

Id. at 5. Reasoned judicial choice in the matter currently pending before us requires, in my view, that we reject plaintiff's facial challenge to the constitutionality of the Maine statute, but does not require that we consider the constitutionality of every possible interpretation or application of the Maine statute. This view is reinforced by taking into account James Madison's contributions to federalist thought and actions. This historical background is especially relevant, in my view, to disputes over supremacy of national legislation and associated issues of interpretation of the Maine statute that was before the district court and is before us in this appeal.

IV. In the American Legal System, a State is a Sovereign

Under fundamental premises of the American legal system, the State of Maine, like all other States of the United States of America, is a sovereign. Each State has authority to govern persons and institutions and their transactions within its territorial boundaries.

I do not understand that any of the briefs before us challenges the sovereignty of states within the Union, and I

do not understand the opinion of the Court of Appeals as challenging this proposition. Thus, I say no more here on the existence of sovereignty of states within the Union. Some important implications of this sovereignty, however, are noted in other sections of this opinion, *infra*.

V. A State May Act in Multiple Roles

A sovereign State of the United States, in addition to governing, may be an active participant in a market for any kind of goods or services that it seeks to buy for its own use, including a purchase for (1) a use such as obtaining furniture for a State office and (2) a use such as obtaining pharmacy products for State-sponsored programs such as Medicaid and Medicare.

Thus, the State of Maine may act

(1) as a sovereign,

(2) as a market participant itself because it buys pharmacy products for Medicaid patients, and

(3) in "the role of each State as a guardian and trustee for its people" who need pharmacy products at affordable prices. *White v. Massachusetts Council of Constr. Employers,* 460 U.S. 204, 207 n.3 (1983).

The third of these roles has special relevance to issues in this case because Maine has undertaken to represent "its people" who need pharmacy products at affordable prices.

It would be a curious irony indeed if dozens of privately organized groups of Pharmacy Benefit Managers (PBMs) could participate freely in the market for purchasing products from pharmacy product manufacturers but States as guardians and trustees for their people could not because the States are also sovereign. In my view, we should make the commonsense ruling that the State of Maine as well as PBMs may participate in the market for purchasing pharmacy products.

Any conflict of interest problems that might theoretically be raised are answered in the distinctive circumstances of this case by the fact that the State of Maine faces no conflicting interests because it believes that in all its roles it is trying to serve the best interests of its people and each of the groups of its people who have an interest in and need for pharmacy products.

VI. Interpreting "Best Efforts" Provisions of the Maine Statute

A. The Statutory Maine Rx Program

By a legislative enactment in the first quarter of the year 2000, the State of Maine established The Maine Rx Program ("the program"). Maine's Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) ("The Act"). The Act established the program "to reduce prescription drug prices for residents of the State." *Id.,* Me. Rev. Stat. Ann. tit. 22, § 2681 (unnumbered introductory paragraph).

> The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a *pharmacy benefit manager* in establishing rebates and discounts on behalf of qualified residents.

Id. (emphasis added).

> The legislation was explicit in declaring program goals.
>
> 1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a *pharmacy benefit manager* in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not

the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

Me. Rev. Stat. Ann. tit. 22, § 2681 (emphasis added).

Some of the statutory definitions of terms are relevant to interpretive issues before us in this appeal.

> 2. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.
>
> * * * *
>
> B. "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus 6%, plus the dispensing fee provided under the Medicaid program under this Title.
>
> * * * *
>
> E. "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.
>
> * * * *
>
> G. "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the State to the participating retail pharmacy.

Id.

Also relevant to the matters before us are the statutory provisions on rebate amount.

> 4. Rebate amount. The commissioner shall *negotiate* the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

> * * * *
>
> B. The commissioner *shall* use the commissioner's *best efforts* to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.
>
> C. With respect to the rebate taking effect no later than October 1, 2001, the commissioner shall use the commissioner's *best efforts* to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.

Id. (emphasis added).

Finally, statutory provisions on discounted prices for qualified residents, in subsection 5, are relevant to the matters before us.

> B. Beginning January 1, 2001, a participating retail pharmacy shall offer the initial discounted price.
>
> C. No later than October 1, 2001, a participating retail pharmacy shall offer the secondary discounted price.

Id.

B. Statutory Interpretation

We should be guided primarily by the plain language of all the provisions of the statute that are relevant to the issues before us, and the plain and ordinary meaning of the words used in all the relevant provisions. The relevant provisions include the definitions in the statute, the declaration of program goals, and the operational directives to Defendant/Appellant Kevin Concannon, Commissioner, Maine Department of Human Services. With these guideposts in mind, I conclude that a reasonable interpretation of the Maine statute includes the following elements:

+ The Maine statute authorizes "best efforts" of Maine administrators rather than requiring prohibitive administrative decisions and actions.
+ The courts should respect the legislative drafters' thoughtful use of the idea of "best efforts."
+ It would be a mistake to accept the suggestions of challenges to the Maine statute that propose to interpret it in a way that, in effect, reads "best efforts" out of the statute.

The provision that opponents describe as requiring authorization for participating pharmacies to offer discounted prices to some defined group of Maine residents and obtain rebates from a state fund, created by an assessment against manufacturers, is *not* a statutory mandate. Instead, the statute requires only "best efforts" of Administrators to achieve the legislative aim of protecting interests of the people of Maine by ongoing creative mediation and negotiation that appeals to the executives of pharmacy products manufacturers to cooperate with Maine's administration of legislatively authorized programs. The statutory provisions providing for "best efforts" and for "negotiation" make clear that the drafters intended the rebate process to entail negotiation and compromise between the state and the manufacturers to reach a mutually beneficial outcome. Although conceivably these "best efforts" could fail, and manufacturers could be subject to the prior authorization provisions of the statute, this outcome is not mandated by the language of the statute, and it is not necessary, in a facial challenge to the statute, to reach questions that may be presented in the future if "best efforts" fail.

As a practical matter, it is obvious that many, probably most, citizens of Maine who have a need for pharmacy products but have less than the economic resources of, say, the top ten percent of citizens of the state, do not have

adequate resources and practical means to get the pharmacy products they need unless

(i) by travel to Canada, or

(ii) by mail, or

(iii) in some other way that involves aid or assistance comparable to that PBMs provide.

If these citizens have a need for prescription medication, and choose to forgo that medication rather than resort to these resources, it may well be in the interests of PhRMA members to negotiate with the State of Maine. In light of allegations made in their submissions, I infer that PhRMA members believe that a rebate in the amount of the Medicaid rebate would not be in their best interest, but the plain language of the statute allows for negotiation in a way that will serve the best interests of both PhRMA members and previously unrepresented citizens of the State of Maine.

VII. The Timing of Adjudications on Constitutionality

The Maine statute, interpreted in the way explained in Part VI, is consistent with all State and Federal constitutional doctrines and is permissible legislation. The district court's ruling to the contrary must be vacated. No federal law (constitutional, statutory, or decisional) preempts and thus forbids reasonable implementation of Me. Rev. Stat. Ann. tit. 22, § 2681.

Properly interpreted, that law is compatible with rather than conflicting with federal Medicaid legislation and administrative supervision of Medicaid.

It is error to say -- as is said in Defendants/Appellants' Brief at page 18 -- that the extent to which the Act advances the purposes of Medicaid is irrelevant. Also, it is error to say that the "proper question" in this appeal "is whether the Act conflicts with the purposes of Medicaid," as Defendants/Appellants' Brief asserts at page 18. The core

question is multifarious, not singular. An evaluative legal test applies, not a bright-line elements legal test.

Plaintiff/Appellee proposes in its waiver and preclusion arguments that we should hold that the fact that Defendants/Appellants make these fallacious arguments bars relief to Defendants/Appellants in this appeal. I would reject this argument. It does not state a valid reason for depriving the citizens of Maine of a fair adjudication of their interests appeal, based on a proper interpretation of the Maine statute. Our federal system permits a State's advocacy in court in support of its interests and those of its people. Penalizing a state and its people whenever the state makes an argument rejected by the court is not appropriate.

Other arguments presented by Defendants/Appellants both here and in the district court are consistent with the interpretation of the Maine statute explained in Part VI of this opinion and support reversal of the judgment of the district court.

An unstated but implicit premise of Plaintiff/Appellee's position in this case is that all Plaintiff/Appellee need do to succeed in a facial challenge to the Maine Act is to show that the administration of the Act is putting pressure on Plaintiff/Appellee, thus making its choice about how it responds to the circumstances developing under ongoing administration of the Act not *entirely* voluntary.

The fallacy of that position stems from the fact that few choices of individuals and entities in a geographical territory that has a government are *entirely* voluntary. True, some transactions are beyond governmental authority to intrude. They are "transactions beyond law" in the sense that individuals and private (non-governmental) entities they create and maintain have a large range of freedom under law to do as they please without governmental intrusion on that freedom. But a demand by any individual or entity for entire freedom is fundamentally in conflict with having a

government that maintains the order essential to protection of individual freedom.

It is possible, as explained in Part VIII, *infra*, to fashion remedies for any threats that may arise from overstepping the bounds of statutorily authorized "best efforts" of Maine's Commissioner of Human Services during the ongoing administration of the Maine Rx Program. It is appropriate to wait and see what happens, and fashion appropriate remedies for any overstepping, rather than declaring Maine's Act unconstitutional because of an outside chance that something beyond constitutional bounds will be attempted unless an advance declaration of facial invalidity of the statute by the district court is allowed to stand.

VIII. Remedies for Threats to Overstep Statutory Authorization

A United States district court, confronted with a facial challenge to validity of a state statute on grounds like those asserted in this case, should dismiss the facial challenge for failure to meet the requirements of applicable precedents.

The court might also find it appropriate to declare explicitly that the dismissal on this ground would not be a bar to an otherwise properly supported claim for relief against a threatened administrative overstepping of the bounds of the statutory authorization for administrative "best efforts" to negotiate and implement a suitable accommodation of legitimate interests by methods acceptable to Maine's Commissioner of Human Services, acting both for the State and as a PBM for its people, and to manufacturers of pharmacy products who wish to market their products in Maine consistently with the Maine Rx Program.

The decision would be one to wait and see, and act then if needed, instead of prohibiting legislatively sponsored administrative aid to the people of Maine because of a

possibility that at some time in the future some administrator will overstep the bounds of the legislative authorization.

For example, acting under this wait-and-see principle, the Court of Appeals would vacate the District Court's preliminary injunction, but at the same time declare that its ruling would not stand as a bar to renewed proceedings in the District Court if at some future time the Legislative or Executive Branch of the sovereign State of Maine, or an Administrative Agency authorized to act to serve the declared legislative aim of the statute in issue, takes action that is an imminent threat to legally protected interests of a person or entity (including any out-of-state as well as any in-state person or entity) claiming a right to market pharmacy products in Maine. An as-applied challenge to state legislation is a more flexible instrument of adjudication, more capable of reaching an outcome tailored to the circumstances and needs of a case at hand than the all-or-nothing nature of a facial challenge to validity.

A federal district or appellate court's acting in advance of overstepping, because of the possibility overstepping might occur in the future, is fundamentally inconsistent with the body of precedents establishing the elements of a successful facial challenge in a federal court to the consistency of a state statute with potentially preemptive federal law. *See, e.g., California Coastal Comm'n v. Granite Rock Co.,* 480 U.S. 572, 579-80 (1987) (holding that state permit requirements were not preempted by federal law, and stating that the party arguing in favor of preemption would have to demonstrate "*that there is no possible* set of conditions that the [state] could place on its permit that would not conflict with federal law - that any state permit requirement is *per se* preempted") (underscoring added). These precedents would require PhRMA to "*that there is no possible*" application of the statute that would not conflict with the structure and purpose of Medicaid. PhRMA cannot meet this burden. It could not

do so even if we softened the legal standard a bit by substituting "reasonably likely" for "possible." PhRMA's facial challenge must be denied.

A federal court's acting in advance of overstepping by state officials, and responding to a facial challenge, is also inconsistent with relevant precedents for a facial challenge on constitutional grounds. In *United States v. Salerno,* 481 U.S. 739 (1987), the Supreme Court stated that "a facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." *Id.* at 745.

It is true that the *Salerno* decision has been criticized in later opinions of some Justices of the Supreme Court. *See, e.g., Washington v. Glucksberg,* 521 U.S. 702, 740 (1997) (Stevens, J., concurring in the judgments) (declaring that the Court has never in fact applied "such a strict standard."); *Janklow v. Planned Parenthood,* 517 U.S. 1174, 1175-76 (1996) (Stevens, J., respecting the denial of the petition for certiorari) (calling the *Salerno* decision "draconian" and declaring that it "does not accurately characterize the standard for deciding facial challenges.").

Salerno, nevertheless, continues to be cited by both the Supreme Court and the Courts of Appeals. *See, e.g., Anderson v. Edwards,* 514 U.S. 143, 155 n.6 (1995); *Reno v. Flores,* 507 U.S. 292, 301 (1993); *Rust v. Sullivan,* 500 U.S. 173, 183 (1991). We need not reach the issue of the applicability of the *Salerno* test, however, because the statute in this case, as explained in Part VI of this opinion, is capable of an interpretation and an application that is respectful of limits imposed by the Constitution.

The application of facial-challenge jurisprudence in the circumstance of this case before the District Court and in this appeal is, in practical effect, a considerable stretch beyond any thus-far-successful facial challenge. If such an

extension of the jurisprudence of facial challenges expressed in decisions of the Supreme Court of the United States is to occur, it is more appropriate that it occur in an opinion of that Court than in an opinion of a Court of Appeals.

My own reading of the array of Supreme Court opinions on this subject, even in light of the ongoing differences both within the Court and among scholars on the applicability of the *Salerno* test, is that precedent points away from rather than toward softening in any way the rigorous requirements for presenting a successful facial challenge to validity of a state statute.

This conclusion is supported not only by the opinions explicitly reasoned as part of the facial-challenge jurisprudence but also by other ongoing developments of federal law.

One ongoing development supportive of the conclusion I propose is the resurgence in recent years of emphasis on the respect that inferior federal courts are directed to show for the freedom of the people of a locality and local governmental institutions to make their own decisions. For illustrative citations, *see* Part IX of this opinion, *infra*. *See also* the Madisonian principles identified in Part III, *supra*. This emphasis is in part a feature of the distinctive version of federalism underlying what is commonly called the American legal system. It is associated with the Supreme Court's invoking the Commerce Clause not for the ordinary purpose of sustaining federal legislation but to strike down state legislation. This emphasis on federalism weighs in favor of sustaining rather than striking down the Maine Rx Program, as explained in Part IX, *infra*.

IX. The Commerce Clause and Concerns of Federalism

The Brief of Washington Legal Foundation and five other associations as Amici Curiae in support of affirming the preliminary injunction ordered by the District Court for the District of Maine argues that the District Court was

correct in "find[ing] that the [Maine Rx] Program violated the Commerce Clause because it attempted to regulate transactions taking place solely outside the State," and in adding, "Maine may have power over what pharmacies later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the price paid in earlier transactions in other states." Brief of Washington Legal Foundation et al. at 6.

A similar position is developed in the Brief Amicus Curiae of the Chamber of Commerce of the United States in Support of Appellee Recommending Affirmance.

> The Commerce Clause [of the United States Constitution] provides that "[t]he Congress shall have Power . . . [t]o regulate Commerce . . . among the several States. . . ." Art. I, § 8, cl. 3. It is long established that, while a literal reading evinces a grant of power to Congress, the Commerce Clause also directly limits the powers of the States. . . . [*Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992) (citing authorities).]

Brief Amicus Curiae of the Chamber of Commerce of the United States in Support of Appellee Recommending Affirmance at 7. The citations relied upon include the following:

> *Healy v. The Beer Institute*, 491 U.S. 324, 336 (1989) ("a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State."); *see generally* Laurence H. Tribe, American Constitutional Law, §6-12 at 1098 (3d ed. 2000)

(referencing "the *per se* principle against extraterritorial state regulation").

Id. at 9.

These arguments are classic illustrations of the controversial efforts that have occurred from time to time to treat the Commerce Clause not only as authorizing legislation by the Congress of the United States but also as constraining state legislation.

Consider, for example, a case emphasized in the Brief of the Chamber of Commerce, *Wyoming v. Oklahoma,* 502 U.S. 437 (1992). Unlike the case before us, this was a direct clash between two States of the Union. Wyoming, a major coal producing State, though not a seller of coal, imposed a severance tax on those who extracted coal. The direct impact of that severance tax on the price of Wyoming coal purchased by four Oklahoma electric utilities was obvious. The Oklahoma legislature passed an act requiring coal-fired electric utilities in Oklahoma to burn a mixture containing at least 10% Oklahoma-mined coal. The utilities reduced their purchases of Wyoming coal. Wyoming's severance tax revenues declined. Wyoming sought relief under the original jurisdiction of the Supreme Court of the United States. The Court accepted Wyoming's complaint and held the Oklahoma act invalid under the "negative" aspect of the Commerce Clause on the reasoning that it "prohibits economic protectionism - that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Id.* at 454. Even so, the Court added that a clearly discriminatory statute will be struck down "unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism," *citing Maine v. Taylor,* 477 U.S. 131 (1986).

I need not and do not consider whether the case before us would qualify for the exception. Instead, I conclude that

the case before us is not one subject to the "negative" rule itself, quite apart from the exception.

Wyoming v. Oklahoma and other opinions of the Supreme Court that have gone farthest in the direction of a "negative" application of the Commerce Clause do not support the proposition that a federal court acts properly when it disregards all the indicia of the State's purpose in establishing the Maine Rx Program to regulate transactions within the territorial boundaries of Maine and to protect the health of the people of Maine. In these circumstances a federal court does not act properly when it makes a judicial "finding" that the State's declaration of purpose is a facade and the real purpose was "to regulate the price paid in earlier transactions in other states."

First. The legislative aim of the Act was fully stated in the Act itself, as explained in Part V1. A of this opinion, *supra*. This is not a case of hidden or obscure aims.

Second. Any suggestion to the contrary in briefs before this court is in disregard of our obligation, and that of the District Court, in reading the statute, to be guided, as stated in Part V1.B of this opinion, by the plain language of the statute, the definitions in the statute, and the plain and ordinary meaning of the words used in the declaration of program goals, in the statutory definitions, and in the operational directives to Maine's Commissioner of Human Services. *See Whiting v. Town of Westerly,* 942 F.2d 18, 21 n.3 (1st Cir. 1991) ("In evaluating a facial challenge to a state law, a federal court must consider any limiting construction that a state court or enforcement agency has proffered.").

Third. As stated in Part VI. B, the provision of the Maine Act that opponents describe as requiring authorization for participating pharmacies to offer discounted prices to some defined group of Maine residents and obtain rebates from a state fund, created by an

assessment against manufacturers, is not a statutory mandate. Instead, it is a statement of aim. The statute requires only "best efforts" of Administrators to achieve the legislative aim of protecting interests of the people of Maine by ongoing creative mediation and negotiation.

Fourth. As stated in Part VI.B, many and probably most citizens of Maine who have a need for pharmacy products would not have adequate resources and practical means to get the pharmacy products they need absent the Maine Rx Program. In the course of the creative mediation and negotiation required by the statute, the pharmaceutical companies themselves may find it is in their best interests to enter into agreements to allow them to reach this previously untapped market for their products.

Fifth. In view of the foregoing four points, it cannot be proper for a federal court to make judicial "findings" contrary to Maine's legislative declarations and on that basis declare that Maine's Act is invalid because "it attempted to regulate transactions taking place solely outside the State" and attempted "to regulate the price paid in earlier transactions in other states." In so doing, the District Court acted beyond its authority.

The ideals of federalism explained above weigh in favor of respect for a state's experimentation and respect for a state's sovereignty. The precedents that govern our examination and that of the District Court of a facial challenge to state legislation are consistent with these ideals of federalism, and indeed are consistent with the delicate balance of power explained by Madison in his early writings.

The District Court's preliminary injunction must be vacated.

X. Conclusion and Order

The decision I would make, for the reasons explained in this concurring opinion, would not bar further

proceedings, either in the civil action in which the preliminary injunction was issued or in a civil action newly filed at some future time, if at that time a showing could be made by the complaining party that the Legislative or Executive Branch of the sovereign State of Maine, or an Administrative Agency authorized to act to serve the declared legislative aim of the statute in issue, had taken action that is a threat to legally protected interests of a person or entity (including any out-of-state as well as any in-state person or entity) making the complaint. That person or entity might appropriately seek a form of limited injunctive relief needed to protect identified interests without deeper intrusions on the State of Maine's legitimate interests than would be necessary and appropriate for that purpose.

For the reasons stated in this opinion, the District Court's preliminary injunction should be vacated, and I concur in the judgment of the Court of Appeals, delivered by Judge Bownes, so ordering.

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff, Appellee,
v.
KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, and MAINE ATTORNEY GENERAL
Defendants, Appellants.

Before
Bownes, *Senior Circuit Judge,*
Keeton and Saris*, *District Judges*

ORDER
Entered: June 13, 2001

Order on Petition by Plaintiff-Appellee For Rehearing En Banc, which subsumes a Petition for a Panel Rehearing.

The panel that heard this case has voted to deny the petition for panel rehearing.

For the following reasons, there can be no action taken on the petition for rehearing en banc. None of the members

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* Of the District of Massachusetts, sitting by designation.

of the panel are eligible to vote on the petition for rehearing en banc. Federal Rule of Appellate Procedure 35(a) provides in pertinent part:

> When Hearing or Rehearing En Banc May Be Ordered. A majority of the circuit judges who are in regular active service may order that an appeal or other proceeding be heard or reheard by the court of appeals en banc.

See United States v. Leichter, 167 F.3d 667 (lst Cir. 1999) (absolute majority of active judges is needed to grant rehearing en banc).

Judges Keeton and Saris are United States District Court Judges and Judge Bownes is a Senior Circuit Court Judge. All of the active Circuit Court Judges with the exception of Chief Judge Torruella have recused themselves from this case. The petition for rehearing en banc must, therefore, be denied.

Chief Judge Torruella wants to be recorded as voting "in favor of rehearing en banc, based on the opinion of the District Court."

Judgment shall issue in accord with the Rules.

By the Court:
Phoebe Morse, Clerk.
By: [JANICE M. O'NEIL]
Chief Deputy Clerk

cc: Bruce C. Gerrity, Esq.
Ann R. Robinson, Esq.
Allen S. Rugg, Esq.
Daniel M. Price, Esq.
Marinn F. Carlson
Kathleen M. Sullivan
Paul Stern, Esq.

Andrew S. Hagler, Esq.
John R. Brautigam, Esq.
Thomas Charles Bradley, Esq.
Arn H. Pearson, Esq.
Steven J. Rosenbaum, Esq.
David H. Remes, Esq.
Daniel J. Popeo, Esq.
Richard A. Samp, Esq.
Edwin D. Schindler

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA
Plaintiff,

v. Civil No. 00-157-B-H

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, ET AL.,
Defendants.

ORDER ON MOTION FOR PRELIMINARY INJUNCTION[1]

When prescription drugs are covered by insurance or Medicaid, volume buying produces substantially lower prices. But when a private citizen purchases on his or her own, the price is much higher.[2] The Maine Legislature has

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[1] The Motion by Maine Council of Senior Citizens and Viola Quirion for Leave to File a Brief of Amicus Curiae in Opposition to Plaintiff's Motion for a Preliminary Injunction is Granted by agreement.

[2] A minority staff report for the U.S. House Committee on Government Reform and Oversight says that the average retail price is 86 percent higher for the elderly than the price charged to the federal government and most favored customers like HMOs. Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District of Maine: Drug Companies Profit at the Expense of Older Americans*, Committee on Government Reform

become concerned over these high prescription prices for Maine citizens. It decided that by using Maine's leverage as a large scale purchaser of drugs in the Medicaid market, it could help these people by requiring manufacturers to provide lower prices for them as well. To that end, the Legislature passed L.D. 2599 and the Governor signed it on May 11, 2000.

The Maine legislation does three things that are challenged in this case: (1) it prohibits profiteering and excessive pricing by drug manufacturers, and creates extensive civil penalties to enforce the prohibition; (2) it prohibits manufacturers from altering their distribution schemes so as to escape the Maine law; and (3) it orders the Commissioner of Human Services to negotiate with the drug manufacturers (all of whom are out-of-state) to provide a rebate every time an uninsured Maine citizen buys a prescription at a pharmacy in Maine. Any manufacturers' rebates go into a new state fund, the Rx Fund. Qualifying Maine citizens purchase their prescription medications from Maine pharmacies at a mandated discount; and the manufacturers' rebates in the Rx Fund reimburse the pharmacies for what they have lost. The incentive to make the manufacturers cooperate is the following: the names of those manufacturers who do not participate are to be made public; and their drugs are to be put on a special listing in Maine's Medicaid program, such that prior authorization will be required before those drugs will be approved for any Medicaid reimbursement.[3]

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and Oversight, U.S. House of Representatives, prepared for Rep. Thomas H. Allen, Oct. 9, 1998, at 8.

[3] The Commissioner has proposed a regulation by which the Maine Medicaid Drug Utilization Committee would review any drug slated to go on such a listing. The Committee could then exempt, for medical reasons, specified drugs from the prior

The plaintiff, an association representing drug manufacturers that account for over 75% of brand name drug sales in the United States, has challenged the Maine legislation on the grounds that it violates the interstate Commerce Clause and is preempted by the federal Medicaid statute.[4] On October 19, 2000, I heard a motion for preliminary injunction.

My conclusion: The Maine Legislature has sound reasons for wanting to assist its uninsured citizens who must cope with astronomical prescription drug prices. But in our country, under our Constitution, states cannot legislate outside their boundaries. Whatever power Maine may have over in-state pharmacies, it cannot legislate the amounts that out-of-state manufacturers obtain when they sell to pharmaceutical wholesalers or distributors out-of-state. That is what Maine has tried to do here, in a roundabout way, but the interstate Commerce Clause will not permit it. As for the small proportion of transactions where the manufacturers sell directly into Maine, the rebate program conflicts with the federal Medicaid program and is therefore preempted. As a result, I find that the plaintiff is entitled to a preliminary injunction preventing the enforcement of essential parts of the Maine legislation.

Analysis

1. *Maine's Prohibition on Unconscionable Prices and Unreasonable Profits.* The statute makes it "illegal profiteering" for a manufacturer to "exact[] or demand[] an unconscionable price" or to "exact[] or demand[] prices or terms that lead to any unjust or unreasonable profit." An Act to Establish Fairer Pricing for Prescription Drugs,

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authorization requirement. *See* Proposed Rule: Rules of the Dep't of Human Servs. § 15, Maine Rx Program (2000).

[4] The defendants have not challenged the plaintiff's standing to bring this constitutional challenge.

§ 2697(2), 2000 Me. Legis. Serv. 786 (S.P. 1026) (L.D. 2599) (West) (to be codified at 22 M.R.S.A. § 2697(2)). It is undisputed on the record before me that all the drug manufacturers represented by the plaintiff are located outside the State of Maine, Bantham Decl. ¶ 6, and that by far the greater bulk of their customers—wholesalers and distributors—are likewise outside Maine. There are limited exceptions. Hannaford Bros. Co., located in Maine, buys directly from Roxane Laboratories, Inc. and Boehringer Ingelheim Pharmaceuticals, Inc.; Bindley Western Drug Company, a distributor, has a subsidiary, J.E. Goold, that is located in Maine; and Progressive Distributors, Inc., another distributor, has a facility in Maine. Bilyk Decl. ¶ 5; Feldman Decl. ¶ 8. Under the contracts with these companies, however, the sale from the manufacturer always occurs at the place of business outside Maine—with the exception of Hannaford Bros. Co.[5] In other words, Bindley Western and Progressive Distributors go to other states to buy their products, then import them to Maine.

Where the manufacturers' sales occur outside of Maine, Maine has no authority to regulate the revenues obtained by the manufacturers. Maine's statutory prohibition on profiteering or excess pricing in such transactions is simply unenforceable. I set forth the caselaw concerning extraterritorial legislation in section (3) below.

2. *The Prohibition on Retaliation.* The statute makes it "illegal profiteering" for a manufacturer to "[i]ntentionally prevent[], lessen[] or restrict[] the sale or distribution of prescription drugs in this State in retaliation for the

[5] It appears that title passes in Maine in the case of Roxane and Boehringer sales to Hannaford Bros., Feldman Decl.¶ 7, and Pfizer, Inc. sales pursuant to the Federal Supply Schedule. McPhillips Decl.¶ 7. The record does not disclose whether any Pfizer sales under the Federal Supply Schedule would be subject to the Maine Rx rebate program.

provisions" of the law. Act, § 2697(2)(D), 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2697(2)(D)). Obviously, manufacturers might enter Maine and undertake activities that would fall under this provision. The plaintiff wants me to declare, however, that if the manufacturers merely alter their distribution channels out-of-state, they cannot be held liable under this provision. Although that seems to be a reasonable conclusion, it is unnecessary and inappropriate for me to rule at this time. *See Ernst & Young v. Depositors Econ. Protection Corp.*, 45 F.3d 530, 538 (1st Cir 1995) (noting that courts should avoid answering hypothetical questions); *National Conference of Catholic Bishops v. Smith*, 635 F.3d 535, 540 (1st Cir. 1981) (observing that court will not speculate and will not decide dispute without sufficient facts). I have no specific actions by manufacturers on which to base such a ruling, and a Maine court might construe this portion of the statute in a narrow way that would avoid any constitutional issue.

3. *The Rebate Program.*

(a) *The Commerce Clause.*

Under the United States Constitution, Article I, section 8, Congress has the power "[t]o regulate commerce with foreign nations, and among several states, and with the Indian tribes." U.S. Const. art. I, § 8, cl. 3. The question is whether Maine has intruded on this Congressional power.

(i) Market Participation. The State argues that I need not reach the constitutional issue concerning its rebate program. It says that it is not really legislating or regulating, but simply exercising its market power as a volume purchaser of prescription medicines in the Medicaid program.[6] The Supreme Court has held that when a state

[6] Under 42 U.S.C. § 1396r-8(a)(1), manufacturers must enter into a rebate agreement with the federal government or individual states in order for their drugs to be covered under the Medicaid

participates in the market as a buyer or seller rather than as a regulator, it is not subject to the restrictions of the interstate Commerce Clause. Instead, as it said in a case that originated in Maine, Supreme Court cases "stand for the proposition that ... 'under the dormant Commerce Clause, a State acting in its proprietary capacity as a purchaser or seller may "favor its own citizens over others."'" *Camps Newfound/Owatonna, Inc. v. Town of Harrison, Maine*, 520 U.S. 564, 592-93 (1997); *accord National Foreign Trade Council v. Natsios*, 181 F.3d 38, 64 (1st Cir. 1999).[7]

But the "citizen favoring" the Supreme Court has allowed states to indulge in, when they are market participants, has always been in the actual transaction—Boston limiting its construction projects to firms that employ 50% Boston residents on those projects, *White v. Massachusetts*, 460 U.S. 204, 206, 215 (1983); South

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program. *See* 42 U.S.C.A. § 1396(b) (West 1992). According to the agreement, a manufacturer provides a rebate to the states each quarter based on information submitted by the states for the amount of drugs paid for under Medicaid. 42 U.S.C.A. § 1396r-8(1)(A). The amount of the rebate is calculated by a formula in the statute, which incorporates the manufacturer's submission of its average manufacturer price and best price for the covered drugs. 42 U.S.C.A. § 1396r-8(c). In addition, the drug rebate program allows states to require that certain drugs be approved before physicians may dispense them, *see* n.12 *infra*, and requires states to conduct drug review prospectively and retrospectively. 42 U.S.C.A. § 1396r-8(d), (g).

[7] This unfortunate terminology—"dormant Commerce Clause"—refers to Supreme Court cases holding that even where Congress has not used its interstate commerce power to legislate on a particular subject (hence, "dormant" or "negative"), states are not free to intrude in ways that burden commerce. Justice Scalia has noted his disagreement with the principle, *General Motors Corp v. Tracy*, 519 U.S. 278, 312-14 (1997), but it remains good law.

Dakota selling its cement only to South Dakota residents, *Reeves, Inc. v. Stakes*, 447 U.S. 429, 440 (1980); Maryland purchasing junked cars from its residents with less paper documentation than from out-of-staters, *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 809-10 (1976). None of the cases supports extending this market power to other activities. Here, Maine is not favoring its citizens in the actual transaction when it buys prescription drugs in the Medicaid program. (An example of permitted favoritism would be buying only from Maine manufacturers, if there were any.) Instead, it is trying to use its leverage there to achieve a social, regulatory goal elsewhere—to reduce the price of prescription medications for Maine citizens who do not participate in Medicaid and who do not have private insurance.[8] That is a worthy legislative goal, but it is not the kind of market participation that the Supreme Court has freed from interstate commerce power limits. In fact, the Supreme Court struck down Alaska's attempt to sell its timber only to customers who would also agree to process the purchased timber in Alaska, *South-Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 96-98 (1984), finding the program to be tantamount to regulation.[9] The Supreme Court reasoned that Alaska was impermissibly trying to use its leverage in the timber market, where it was a participant, in order "to exert a regulatory effect in the processing

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[8] According to the statute, "the State shall serve as a pharmacy benefit manager...." Act, § 2681, 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2681). The State does not, however, buy the drugs. If it did, the analysis and result might be different.

[9] The Court also struck down Wisconsin's refusal to make any state purchases from repeat labor law violators, *Wisconsin Dep't of Industry, Labor & Human Relations v. Gould, Inc.*, 475 U.S. 282, 289 (1986), on the same ground, that it was in fact a regulatory measure.

market, in which it is not a participant." 467 U.S. at 98. Likewise here, Maine is using its leverage in the Medicaid market, where it is a participant, to exert a regulatory effect in the uninsured market for prescription drugs, in which it is not a participant. As the First Circuit has observed (quoting approvingly from the *Wunnicke* plurality decision): "the market participant 'doctrine is not carte blanche to impose any conditions that the State has the economic power to dictate, and does not validate any requirement merely because the State imposes it upon someone with whom it is on contractual privity.'" *National Foreign Trade Council*, 181 F.3d at 63. As a result, Maine's Rx program cannot escape interstate Commerce Clause limitations.

(ii) Constitutionality. Treating the rebate program as an exercise of Maine's regulatory or police power, then, I must decide whether it is constitutional. First, the State is correct that this is not the typical attempt to favor in-state businesses over out-of-state businesses. There are no Maine drug manufacturers, and no suggestion on this record that Maine is in the process of trying to establish a favorable environment to bring them here. Instead, the rebate program applies to any manufacturer, whether or not it is from Maine. Maine is trying to benefit its residents, specifically those who are uninsured, in the purchase of prescription medicines; but it is not trying to better their lot over out-of-staters.[10] So the question is not whether Maine is discriminating against out-of-staters, but simply whether it has the power to extend its authority to out-of-state manufacturers. I conclude that the answer for most transactions is "no," on bedrock principles concerning the

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[10] Of course, if the drug manufacturers are unwilling just to give up their profits, any lowering of prices to uninsured Maine consumers will have to result in an increase somewhere else—prices to out-of-state buyers, or in Maine's Medicaid program, or in insured purchases.

territorial limits of a state's power established by the Supreme Court at least as far back as 1935.

In *Baldwin v. G.A.F. Seelig*, Justice Cardozo wrote:

> New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there. So much is not disputed. New York is equally without power to prohibit the introduction within her territory of milk of wholesome quality acquired in Vermont, whether at high prices or at low ones. This again is not disputed.

294 U.S. 511, 521 (1935). If we change the names of the states, and substitute prescription medications for milk, the statements are equally applicable here to distributors that acquire prescription drugs outside the state of Maine before they bring them here. Maine may have power over what pharmacists later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the prices paid earlier in transactions in other states. The Supreme Court reiterated these principles as recently as 1989:

> Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions: First, the "Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State," . . . . Second, a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the

> practical effect of the regulation is to control conduct beyond the boundaries of the State.

Healy v. Beer Institute, 491 U.S. 324, 336 (1989) (internal citations omitted). It is undisputable that the practical effect of what Maine has done here is to limit the revenue an out-of-state manufacturer can obtain when it sells drugs to out-of-state distributors that ultimately send or bring the drugs to Maine. Under the Maine rebate program, whatever price the manufacturer originally received for that out-of-state transaction is automatically reduced when the drug comes to Maine. Because Maine has no power thus to extend its power extraterritorially and to impose this burden on interstate commerce, it is irrelevant whether its program actually discriminates against out-of-staters. *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986) (stating that state statutes are struck down if they favor in-state economic interests over out-of-state, *or* if they discriminate against interstate commerce *or* if they simply regulate interstate commerce directly, whether or not they discriminate). *Accord Edgar v. MITE Corp.*, 457 U.S. 624, 644 ("Insofar as the Illinois law burdens out-of-state transactions, there is nothing to be weighed in the balance to sustain the law."); Laurence H. Tribe, *American Constitutional Law* § 6-8 (3d ed. 2000).

(b) *Supremacy Clause*. The plaintiff manufacturers concede that the Commerce Clause limitations on Maine's power to legislate outside its borders do not prevent Maine from regulating sales to Maine-based distributors (*e.g.*, Hannaford Bros., J.E. Goold, Progressive Distributors). Instead, I must decide whether the federal Medicaid program invalidates Maine law as to such transactions by virtue of the Supremacy Clause.

Under Article VI of the United States Constitution:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof;

> and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land, and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI. There is no question that Congress has legislated an extensive and detailed federal Medicaid program. But nowhere has it expressly forbidden what Maine has done.[11] The Supremacy Clause issue, therefore, is whether there is "implied" preemption on the basis that Maine's legislation is inconsistent with Medicaid's objectives. This inquiry boils down to a question of Congressional intent. *See Pacific Gas v. State Energy Resources Conserv. & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983); *Massachusetts Ass'n of HMOs v. Ruthhardt*, 194 F.3d 176, 178 (1st Cir. 1999); *O'Brien v. Massachusetts Bay Trans. Auth.*, 162 F.3d 40, 43 (1st Cir. 1998).

"Preemption may, of course, be inferred from the goals of a federal statute." *French v. Pan Am Express, Inc.*, 869 F.2d 1, 5 (1st Cir. 1989). The purposes of the federal Medicaid program are straightforward: to provide medical services, including prescription drugs, 42 C.F.R. §§ 456.702-3 (West 2000), to those with medical needs who qualify under Medicaid's eligibility standards. 42 U.S.C.A. § 1396 (West 1992); *Mayburg v. Secretary of Health & Human Servs.*, 740 F.2d 100, 103 (1st Cir. 1984) (noting the general principle that the Social Security Act should be broadly construed "to carry out Congress's intent to provide

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[11] Congress recognizes the existence of prior authorization programs for prescription drugs and specifies two requirements: (1) a 24-hour response to any request for authorization; (2) a 72-hour emergency supply where authorization is unavailable. 42 U.S.C.A. § 1396r-8(d)(5) (West 1992). Maine satisfies both requirements. *See* Code Me. R. §§ 80.07-3-80.07-4 (1979).

medical expense coverage for all qualifying individuals"). To that end, Congress has demanded that any state restriction on drug distribution "provide such safeguards as may be necessary to assure that care and services ... will be provided, *in a manner consistent with the best interest of Medicaid's requirements*." 42 U.S.C.A. § 1396c(a)(19) (West 1992) (emphasis added). Nowhere has Congress suggested that the federal Medicaid program can be used to further the interests of *non*-Medicaid recipients. Maine asserts that under its proposed regulations Maine will comply with federal requirements; that the "Department of Human Services will not deny a single Medicaid recipient access to the safest and most efficacious prescription drug therapy indicated for their individual medical circumstances." Def. Mem. in Opp'n to Mot. for Prelim. Inj. at 29. But Maine can point to no *Medicaid* purpose in this new prior authorization requirement that Maine has added for Medicaid prescription drugs. Maine has not just passed a law that might conflict with the objectives of a federal law. It has actually taken the federal Medicaid program and altered it to serve Maine's local purposes. If Maine can use its authority over Medicaid authorization to leverage drug manufacturer rebates for the benefit of uninsured citizens, then it can just as easily put the rebates into a state program for highway and bridge construction or school funding. All these purposes are outside the scope of the federal Medicaid program. No matter how modest an obstacle the new prior authorization amounts to (the parties disagree on the severity of the obstacle), it is an obstacle—drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed or prescribed—and therefore "an obstacle to the accomplishment and execution of the Congressional objectives of federal Medicaid." *See Pacific Gas*, 461 U.S.

at 402-03; *Ruthhardt*, 194 F.3d at 178; *Beckley Capital Ltd. P'ship v. DiGeronimo*, 184 F.3d 52, 56 (1st Cir. 1999); *O'Brien*, 162 F.3d at 43.[12] The Supremacy Clause prevents

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[12] It may never have occurred to Congress that the Medicaid program could be hijacked to provide leverage for other purposes. Instead, the legislative history reveals that Congress contemplated prior authorization only in narrow circumstances: "As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care." H. Rep. No. 101-881 at 98 (Oct. 16, 1990) *reprinted in* 1990 U.S.C.C.A.N. 2016-1, 2110. Maine's Rx rebate program has nothing to do with these concerns of unnecessary use of prescription drugs or with safeguarding Medicaid payments.

The Secretary (here, HCFA) has not promulgated a final regulation on prior authorization, *see* 65 Fed. Reg. 22802, 22805 (Apr. 24, 2000), and therefore I do not apply *Chevron* analysis under *Visiting Nurses Ass'n of North Shore, Inc. v. Bullen*, 93 F.3d 997, 1006-09 (1st Cir. 1996). *See Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 n.15 (11th Cir. 1999) (refusing to give the FDA's proposed rule any authoritative weight or deference); *Public Citizen, Inc. v. Shalala*, 923 F. Supp. 13, 18 n.6 (D.D.C. 1996) (noting that "tentative conclusion articulated in a nonfinal proposed rules does not command deference from the Court nor is it binding on the agency"). *But see Vanscoter v. Sullivan*, 920 F.2d 1441, 1445 (9th Cir. 1990) (deferring to agency interpretation expressed in a proposed rule). A comment (comments are not entitled to deference, *Visiting Nurses Ass'n*, 93 F.3d at 1007) concerning the proposed regulation does support the proposition that prior authorization can be used for clinical or economic purposes and refers approvingly to a state seeking a larger rebate. Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48442, 48473 (Sept. 19, 1995). But there is *no* suggestion that HCFA was discussing anything other than a larger rebate that would benefit the *Medicaid* program.

Maine from diverting the Medicaid program to this other objective, however worthy an objective it may be.

(c) *Voluntariness*. The State has not argued directly that its rebate/Rx program is voluntary and therefore not to be considered a forbidden exercise of state power. But there is the flavor of such an argument—that this is all just a matter of negotiation with the Commissioner—and I therefore address it. Is negotiation and participation in the rebate program simply a voluntary decision that out-of-state manufacturers make for the greater good? If public listing of those refusing to negotiate with the Commissioner were the only incentive, I would find no serious constitutional issue. Nothing prevents a state from seeking voluntary largess from companies, even out-of-state companies, and then publicly recognizing them for their civic-mindedness or publicly stigmatizing those who do not participate for their lack of civic-mindedness. There is likewise no prohibition on the Commissioner merely negotiating with companies to try to persuade them to take action that will lower the prices to Maine citizens. Instead, the bite here—if there is any—is the new condition that drugs of an uncooperative manufacturer require prior approval before they can qualify for Medicaid reimbursement. Indeed, the statute says that manufacturers "shall enter" into rebate agreements and speaks of negotiating the "rebate *required* from a manufacturer." Act, § 2681(3), (4), 2000 Me. Legis. Serv. 786 (2000) (to be codified at 22 M.R.S.A. § 2681(3), (4)) (emphasis added).[13] It is only common sense to conclude

[13] The L.D. that was ultimately enacted came from Senate Amendment A of May 11, 2000, to S.P. 1026, L.D. 2599. According to the Senate Amendment "A" Summary, the amendment "directs the department to require prior authorization for the dispensing of drugs in the Medicaid program that are provided from manufacturers and labelers who do not enter into

that the requirement has been put in the legislation because the Legislature thought it would create *some* bite to give the Commissioner negotiating leverage for the Rx rebate program. The State makes no argument that the new condition of prior approval serves any purpose of the Medicaid program.[14] And the State has not contested the plaintiff's affidavits that a prior authorization listing often results in substantially reduced market share for a manufacturer. *See, e.g.*, Moules Aff. ¶¶ 7, 9-4; Bilyk Decl. ¶ 6. It is, therefore, not a voluntary program.

But only the prior approval requirement creates the coercion that makes the rebate/Rx program unconstitutional. If the State wants to continue the program as a voluntary program with public stigma being the only incentive, it may do so.

rebate agreements with the State under the Maine Rx Program." ¶ 6.

[14] Instead, the Medical Director for the Maine Bureau of Medicaid Services, which administers Maine's Medicaid Program, states that the "primary purpose of a prior authorization requirement is to ensure that a drug is not being used inappropriately" and is not designed "to limit the use of that drug." Clifford Aff. ¶¶ 6, 7. Indeed, the Commissioner has recently proposed a regulation to make clear that medically necessary drugs will still be approved and in some instances may even escape the prior authorization requirement despite a manufacturer's failure to negotiate a rebate. *See* Proposed Rule: Rules of the Dep't of Human Servs., § 15, Maine Rx Program (2000) (to be codified at Code Me. R. § 15). The reason for this narrowing of the program is apparently to forestall Medicaid challenges and, according to the Assistant Attorney General at oral argument, to recognize that the Department is directed to "impose prior authorization requirements in the Medicaid program under this title, *as permitted by law*...." Act, § 2681(7), 2000 Me. Legis. Serv. 786 (West) (to be codified at 22 M.R.S.A. § 2681(7)) (emphasis added).

CONCLUSION

For purposes of the preliminary injunction motion, the record is essentially undisputed. On that record, I find the plaintiff's likelihood of success on the merits of most of its constitutional challenges to be overwhelming. That being so, the State's interest in forestalling the preliminary injunction is weak. The State has a strong interest in assisting its economically and medically needy citizens, but not through unconstitutional legislation. The public interest is the same. The plaintiff's interest is strong because, under the Eleventh Amendment manufacturers would be unable to recover payments they made to the State, and by entering the rebate agreements, may be submitting themselves contractually to an obligation, regardless. Accordingly, the plaintiff is entitled to a preliminary injunction, *see Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670, 673-74 (1st Cir. 1998); *Ross-Simons of Warwick, Inc. v. Baccaral, Inc.*, 102 F.3d 12, 15 (1st Cir. 1991). No security is appropriate under Fed. R. Civ. P. 65(c), and the State has not requested security.

The Commissioner is hereby PRELIMINARILY ENJOINED from penalizing manufacturers, by placing their drugs on prior listing status, for refusing to negotiate or to pay a rebate to Maine's Rx program.

The Attorney General is hereby PRELIMINARILY ENJOINED from seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine, even if the prescription drugs eventually end up and are ultimately purchased in Maine.

SO ORDERED.

DATED THIS [26th] DAY OF OCTOBER 2000.

[signed]
D. BROCK HORNBY
UNITED STATES DISTRICT JUDGE

SOCIAL SECURITY ACT § 1927
42 U.S.C. § 1396r-8 (in pertinent part)

§ 1396r-8. Payment for covered outpatient drugs.

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), * * *

* * * *

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary--

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1)

of this section) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement, and

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs.

* * * *

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of--

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of--

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified

in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning--

* * * *

(V) after December 31, 1995, is 15.1 percent.

* * * *

(C) Best price defined

For purposes of this section--

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding--

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section;

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State

pharmaceutical assistance program; and

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

(ii) Special rules

The term "best price"--

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of--

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which--

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar

quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

* * * *

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee

consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval--

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

* * * *

(k) Definitions

In this section--

(1) Average manufacturer price

The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

* * * *

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in--

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

* * * *

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug

Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the State during the period.

(ii) Innovator multiple source drug

The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug

The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception

Subparagraph (A)(1)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(1)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph--

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

* * * *

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

STATE OF MAINE

IN THE YEAR OF OUR LORD
TWO THOUSAND

S. P. 1026 -L. D. 2599
An Act to Establish Fairer Pricing for Prescription Drugs

Be it enacted by the People of the State of Maine as follows:

PART A

Sec. A-l. 5 MRSA §12004-I, sub-§47-E is enacted to read:

47-E Human Services	Prescription Drug Advisory Commission	Expenses Legislative Per Diem For Nonsalaried Or Nonpaid Public Members	22 MRSA §2692, sub-§6

Sec. A-2. 22 MRSA §254-B, as enacted by PL 1999, c. 431, §1, is repealed.

Sec. A-3. 22 MRSA c. 603 is enacted to read:

CHAPTER 603
PRESCRIPTION DRUG ACCESS
SUBCHAPTER I

MAINE RX PROGRAM

§2681. Maine Rx Program established

The Maine Rx Program, referred to in this Subchapter as the "program," is established to reduce prescription drug prices for residents of the State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

1. Program Goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. It is not the intention of the State to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified Maine residents under this subchapter.

2. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Average wholesale price" means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

B. "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus 6%, plus the dispensing fee provided under the Medicaid

program under this Title.

C. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

D. "Participating retail pharmacy" or "retail pharmacy" means a retail pharmacy located in this State, or another business licensed to dispense prescription drugs in this State, that participates in the program and that provides discounted prices to residents as provided in subsection 5.

E. "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.

F. "Qualified resident" means a resident of the State who has obtained from the department a Maine Rx enrollment card.

G. "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the State to the participating retail pharmacy.

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section 254 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

A. The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

C. With respect to the rebate taking effect no later than October 1, 2001, the commissioner shall use the commissioner's best efforts to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government.

5. Discounted prices for qualified residents. Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to subsection 3 shall discount the retail price of those drugs sold to qualified residents.

A. The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead and incentive payments.

B. Beginning January 1, 2001, a participating retail pharmacy shall offer the initial discounted price.

C. No later than October 1, 2001, a participating retail pharmacy shall offer the secondary discounted price.

D. In determining the amount of discounted prices, the department shall consider an average of all rebates

provided pursuant to subsection 4, weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available.

6. Operation of program. The requirements of this subsection apply to participating retail pharmacies.

A. The Maine Board of Pharmacy shall adopt rules requiring disclosure by participating retail pharmacies to qualified residents of the amount of savings provided as a result of the program. The rules must consider and protect information that is proprietary in nature. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

B. The department may not impose transaction charges under this program on retail pharmacies that submit claims or receive payments under the program.

C. A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under subsection 5.

D. On a weekly or biweekly basis, the department must reimburse a participating retail pharmacy for discounted prices provided to qualified residents under subsection 5 and professional fees, which must be set by the commissioner. The amount of the initial professional fee must be set at $3 per prescription.

E. The department shall collect utilization date from the participating retail pharmacies submitting claims necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulations.

7. Action with regard to nonparticipating manufacturers and labelers. The names of manufacturers and labelers who do not enter into rebate agreements

pursuant to this subchapter are public information. The department shall release this information to health care providers and the public. The department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.

8. Discrepancies in rebate amounts. Discrepancies in rebate amounts must be resolved using the process established in this subsection.

A. If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

B. If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

C. Following the procedures established in paragraph A or B, either the department or the manufacturer or labeler may request a hearing before the Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

9. Dedicated fund. The Maine Rx Dedicated Fund, referred to in this section as the "fund," is established to receive revenue from manufacturers and labelers who pay rebates as provided in subsection 4 and any appropriations or allocations designated for the fund. The purposes of the fund are to: reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to subsection 5; to reimburse the department for contracted services, administrative and associated computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs; and to benefit the elderly low-cost drug program under section 254. The fund also must be used in fiscal year 2002-03 to repay the working capital advance made to the program during fiscal year 2000-01 from the Trust Fund for a Healthy Maine, established in section 1512. The fund is a nonlapsing dedicated fund. Interest on fund balances accrues to the fund. Surplus funds in the fund must be used for the benefit of the program. Notwithstanding Title 5, section 1585, surplus funds may also be transferred to the elderly low-cost drug program established under section 254.

10. Annual summary report. The department shall report the enrollment and financial status of the program to the Legislature by the 2nd week in January each year.

11. Obligations of department. The department shall establish simplified procedures for determining eligibility and issuing Maine Rx enrollment cards to qualified residents and shall undertake outreach efforts to build public awareness of the program and maximize enrollment of qualified residents. The department may adjust the requirements and terms of the program to accommodate any new federally funded prescription drug programs.

12. Contracting. The department may contract with a 3rd-party or 3rd-parties to administer any or all components of the program, including, but not limited to, outreach, eligibility, claims, administration and rebate recovery and

redistribution.

13. Medical assistance programs. The department shall administer the program and other medical and pharmaceutical assistance programs under this Title in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this subsection the department may coordinate the other programs and this program and may take actions to enhance efficiency, reduce the cost of prescription drugs and maximize the benefits to the programs and enrollees, including providing the benefits of this program to enrollees in other programs.

14. Rulemaking. The department may adopt rules to implement the provisions of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

15. Waivers. The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this subchapter.

SUBCHAPTER II
PRESCRIPTION DRUG PRICE REDUCTION ACT

§2691. Short Title; purpose

This subchapter may be known and cited as the "Prescription Drug Price Reduction Act." The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature as a positive measure to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare of Maine residents.

§2692. Prescription Drug Advisory Commission

The Prescription Drug Advisory Commission, referred to in this subchapter as the "commission," is established to review access to and the pricing of prescription drugs for residents of the State, to advise the commissioner on prescription drug pricing and to provide periodic reports to the commissioner, the Governor and the Legislature.

1. Membership. The commission consists of the following 12 members:

A. Three members of the public, appointed by the President of the Senate, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

B. Three members of the public, appointed by the Speaker of the House, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

C. Two members of the health care community who are authorized by the laws of this State to prescribe drugs, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term;

D. Two pharmacists, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term. To be appointed to and remain on the commission, each pharmacist must:

(1) Be licensed to practice pharmacy and be engaged in the practice of retail pharmacy in this State;

(2) Have at least 5 years of experience in this State as a licensed pharmacist; and

(3) Be a resident of this State; and

E. The Director of the Bureau of Medical Services and the Commissioner of Professional and Financial Regulation, or their designees, who shall serve as ex officio, nonvoting members.

2. Terms. With the exception of the initial appointees, all members of the commission serve for terms of 3 years and may be reappointed. With the exception of the pharmacist members, if the profession or qualifications of a commission member change during the term of commission membership, the member may continue to complete the term for which the appointment was made.

3. Meetings; chair. The commission shall meet at least 4 times per year. The members shall select a chair from among the members. Additional meetings may be called by the chair.

4. Duties. The duties of the commission include the following:

A. To review access to prescription drugs for residents of the State, including, but not limited to, pricing and affordability information;

B. To advise the commissioner on access to prescription drugs and prescription drug prices, including, but not limited to, insurance and 3rd-party payments for prescription drugs, the need for maximum retail prices, and, if maximum retail prices are established, the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices;

C. To advise the commissioner on the adoption of rules necessary to implement this subchapter; and

D. To report to the commissioner, the Legislature and the Governor by April 1, 2001, and annually thereafter by the 2nd week in January, including in the report any recommendations for action regarding access to and the pricing of prescription drugs.

5. Staffing. The department shall provide staffing for the commission.

6. Compensation. Public members not otherwise compensated by their employers or other entities whom they represent are entitled to receive reimbursement of necessary expenses and a per diem equal to the legislative per diem for their attendance at authorized meetings of the commission.

7. Cooperation. In performing its duties, the commission shall work with the department, the Maine Board of Pharmacy and the Department of Professional and Financial Regulation.

§2693. Emergency drug pricing

In order to achieve the public health purposes listed in section 2691, maximum retail prices for prescription drugs sold in Maine may be established pursuant to this section.

1. Emergency drug pricing procedures. The following provisions apply to determinations regarding maximum retail prices for prescription drugs and to the procedures for establishing those prices.

A. By July 1, 2002, the department shall adopt rules establishing the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail process of selected drugs and the procedures for phasing out or terminating maximum retail prices. Prior to adopting rules pursuant to this paragraph, the commissioner shall consult with and consider the

recommendations of the commission regarding the rules.

B. By January 5, 2003, the commissioner shall determine whether the cost of prescription drugs provided to qualified residents under the Maine Rx Program pursuant to subchapter I is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in the State. In making this determination the following provisions apply.

(1) The commissioner shall review prescription drug use in the Medicaid program using data from the most recent 6-month period for which data is available.

(2) Using the data reviewed in subparagraph (1), the commissioner shall determine the 100 drugs for which the most units were provided and the 100 drugs for which the total cost was the highest.

(3) For each prescription drug listed in subparagraph (2), the commissioner shall determine the cost for each drug for qualified residents provided those drugs under the Maine Rx Program on a certain date. The average cost for each such drug must be calculated.

(4) For each prescription drug listed in subparagraph (2), the commissioner shall determine the lowest cost for each drug paid by any purchaser on the date that is used for subparagraph (3) delivered or dispensed in the State, taking into consideration the federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the Maine Rx Program. The average cost for each such drug must be calculated.

(5) If the average cost for one or more prescription drugs under the Maine Rx Program as

determined in subparagraph (3) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subparagraph (4), the commissioner shall establish maximum retail prices for any or all prescription drugs sold in the State. Maximum prescription drug prices established under this subparagraph must take effect July 1, 2003.

C. In establishing maximum retail prices under this paragraph, the commissioner shall consider the advice of the commission and shall follow procedures set forth by rules adopted by the department.

D. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.

2. Select prescription drugs. In making a determination under this section the commissioner may rely on pricing information on a selected number of prescription drugs if that list is representative of the prescription drug needs of the residents of the State and is made public as part of the process of establishing maximum retail prices.

3. Public health or welfare. The commissioner may take actions that the commissioner determines necessary if there is a severe limitation or shortage of or lack of access to prescription drugs in the State that could threaten or endanger the public health or welfare.

4. Appeals. A retailer of prescription drugs may appeal the maximum retail price of a prescription drug established pursuant to this section in accordance with the Maine Administrative Procedure Act.

5. Enforcement. A violation of the maximum retail prices established under this section is a violation of the Maine Unfair Trade Practices Act.

§2694. Rulemaking

With the exception of rules designated in this subchapter as major substantive rules, rules adopted pursuant to this subchapter are routine technical rules as defined by Title 5, chapter 375, subchapter II-A.

SUBCHAPTER III

PROFITEERING IN PRESCRIPTION DRUGS

§2697. Profiteering in prescription drugs

Prescription drugs are a necessity of life. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs.

1. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

B. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

2. Profiteering. A manufacturer, distributor or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:

A. Exacts or demands an unconscionable price;

B. Exacts or demands prices or terms that lead to any unjust or unreasonable profit;

C. Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or

D. Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

3. Right of action and damages. The State may bring a civil action in District Court or Superior Court for a direct or indirect injury to any person, group of persons, the State or political subdivision of the State caused by a violation of this subchapter. There is a right to a jury trial in any action brought in Superior Court under this section. If the State prevails, the defendant shall pay 3 times the amount of damages and the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees. For a willful or repeated violation of this section, punitive damages may be awarded. After deduction of the costs of distribution, the damages must be equitably distributed by the State to all injured parties.

4. Civil violation. Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed $100,000, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

5. Unfair trade practice. A violation of this section is also a violation of the Maine Unfair Trade Practices Act.

§2693. Investigation by Attorney General

The Attorney General, upon the Attorney General's own initiative or upon petition of the commissioner or of 50 or more residents of the State, shall investigate suspected violations of this subchapter.

The Attorney General may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the Attorney General related to any such matter under investigation. The summons must be served in the same manner as summonses for witnesses in criminal cases, and all provisions of law related to criminal cases apply to summonses issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside. The expense of the investigation must be paid from the appropriation provided in Title 5, section 203.

A Justice of the Superior Court may by order, upon application of the Attorney General, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the Attorney General in the same manner and to the same extent as before the Superior Court. Any failure to obey such an order may be punishable by that court as a contempt.

Sec. A-4. Agreements with governments of other jurisdictions and other entities. The State may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions and with other public and private entities for the purpose of reducing prescription drug prices for residents of the State.

Sec. A-5. Findings; intent; purpose.

1. Findings. The Legislature makes the following findings.

A. Pharmaceutical companies are charging the

citizens of Maine excessive prices for prescription drugs, denying Maine citizens access to medically necessary health care and thereby threatening their health and safety. Many Maine citizens are admitted to or treated at hospitals each year because they can not afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they can not afford their necessary prescription drugs that could have supported them outside of an institution. All Maine citizens are threatened by the possibility that when they need medically necessary prescription drugs most they may be unable to afford their doctor's recommended treatment.

B. Citizens of Maine and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies.

C. Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates.

D. Excessive pricing for prescription drugs threatens Maine's ability to assist with the health care costs of Maine citizens, undermines the financial capacity of Maine communities to meet the educational needs of Maine children, hurts the ability of the Maine business community to provide health insurance coverage to Maine's work force and has a negative effect on Maine's economy. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents.

2. Intent. It is the intent of the Legislature to provide access for all Maine citizens to medically necessary prescription drugs at the lowest possible prices.

3. Purpose. This law is enacted by the Legislature as a

positive measure to make prescription drugs more affordable for Maine residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities and increasing the public health and welfare.

Sec. A-6. Appointments; first meeting of Prescription Drug Advisory Commission. All appointments must be completed no later than 30 days following the effective date of this Act. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. The Chair of the Legislative Council shall call the first meeting of the commission within 30 days after notification that appointments have been completed. At the first meeting of the commission, the members shall select a chair from among the members.

Sec. A-7. Working capital advance. Notwithstanding the Maine Revised Statutes, Title 22, section 1511, subsection 3 and section 1512, the State Controller is authorized to advance to the Maine Rx Dedicated Fund in the Department of Human Services $4,582,500 from the Trust Fund for a Healthy Maine no later than January 1, 2001. These funds may be allotted by financial order upon the recommendation of the State Budget Officer and approval of the Governor. These funds must be returned to the Trust Fund for a Healthy Maine from the Maine Rx Dedicated Fund no later than June 30, 2005.

Sec. A-8. Appropriation. The following funds are appropriated from the General Fund to carry out the purposes of this Part.

HUMAN SERVICES, DEPARTMENT OF 2000-01

Maine Rx Program

Positions – Legislative Count	(6.000)
Personal Services	$148,330
All Other	$502,750

Provides for the one-time appropriation of funds to establish the Maine Rx Program, including the establishment of 6 additional positions and related operating costs, for outreach activities, to contract for claims management and services and for costs associated with the issuance of prescription cards.

DEPARTMENT OF HUMAN SERVICES	
TOTAL	$651,080

ATTORNEY GENERAL, DEPARTMENT OF THE

Administration – Attorney General

Positions – Legislative Count	(1.000)
Personal Services	$46,745
All Other	$5,340
TOTAL	$52,085

Provides one-time funds for one Assistant Attorney General position and related operating costs due to the establishment of

the Maine Rx Program.

Fair Drug Pricing Contingent Account

All Other	$130,000

Provides one-time funds to support litigation costs associated with the Maine Rx Program. Any balance remaining at the end of each fiscal year may not lapse but must be carried forward to be used for the same purpose.

DEPARTMENT OF THE ATTORNEY GENERAL	
TOTAL	$182,085
TOTAL APPROPRIATIONS	$833,165

Sec. A-9. Allocation. The following funds are allocated from the Other Special Revenue funds to carry out the purposes of this Part.

PROFEFSSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF	2000-01

Licensing and Enforcement

All Other	$2,500

Provides for the allocation of funds for the costs associated with the Maine Board of Pharmacy to adopt rules associated with

the Maine Rx Program.

PART B

Sec. B-1. 22 MRSA §254, sub-§8, as corrected by RR 1999, c. 1, §27, is amended to read:

8. Drug rebate program. Effective May 1, 1992, payment must be denied for drugs from manufacturers that do not enter into a rebate agreement with the department for prescription drugs included in the list of approved drugs under this program. Each agreement must provide that the pharmaceutical manufacturer make rebate payments for both the basic and supplemental components of the program to the department according to the following schedule.

~~A. For the period beginning May 1, 1992 and ending September 30, 1992, the rebate percentage is equal to 11% of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of dosage units reimbursed to providers of prescription drugs during the period for which payment is due.~~

B. For the quarters beginning October 1, 1992, the rebate percentage is equal to the percentage recommended by the federal Health Care Financing Administration of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of

dosage units reimbursed to providers of prescription drugs during the period for which payments are due.

C. Beginning October 1, 1998, the department shall seek to achieve an aggregate rebate amount from all rebate agreements that is 6 percentage points higher than that required by paragraph B of this subsection, provided such rebates result in a net increase in the rebate revenue available to the elderly low-cost drug program. In the event the department is not able to achieve the rebate amount required by this paragraph without compromising the best interest of recipients of the elderly low-cost drug program, it shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over appropriations and financial affairs in the First Regular Session of the 119th Legislature.

Upon receipt of data from the department, the pharmaceutical manufacturer shall calculate the quarterly payment. If a discrepancy is discovered, the department may, at its expense, hire a mutually agreed-upon independent auditor to verify the pharmaceutical manufacturer's calculation. If a discrepancy is still found, the pharmaceutical manufacturer shall justify its calculation or make payment to the department for any additional amount due. The pharmaceutical manufacturer may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the department. If a discrepancy is discovered, the department shall justify its data or refund any excess payment to the pharmaceutical manufacturer.

If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation must be submitted to the Administrative Hearings Unit. Failure to resolve the dispute may be cause for terminating the drug rebate agreement and denying payment to the

pharmaceutical manufacturer for any drugs.

~~All prescription drugs of a pharmaceutical manufacturer who enters into an agreement pursuant to this subsection that appear on the approved list of drugs must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements.~~ Any prescription drug of a manufacturer that does not enter into an agreement is not reimbursable unless the department determines the prescription drug is essential.

All prescription drugs of a pharmaceutical manufacturer that enters into an agreement pursuant to this subsection that appear on the list of approved drugs under this program must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements, except as provided in this paragraph. If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the elderly low-cost drug program requiring the use of a drug formulary and prior authorization for the dispensing of certain drugs to be listed on a formulary. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

Sec. B-2. 22 MRSA §254, sub-§8-A is enacted to read:

8-A. Participation requirement. Beginning January 1, 2001, all manufacturers and labelers of drugs that participate in the Medicaid program under this Title must participate in the drug rebate program under subsection 8. For the purposes of this subsection, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

Sec. B-3. 22 MRSA §3174-Y is enacted to read:

§3174-Y. Prior authorization in Medicaid program

If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs determined to be priced above the established maximum retail prices. The department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs provided from manufacturers and labelers who do not enter into agreements with the department under section 2681, subsection 3. For the purposes of this section, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).